

US3462421 (Prod: Crisor, LLC)

Generated By: KC Joubran

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US3462421

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 20:46:57

Generated On: 09 Jun 2021 17:41:44

[Participant ID](#)

US3462421

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

US3462421

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 02:06:05

Generated On: 09 Jun 2021 17:41:44

Date of Birth (MMM yyyy)	(b) (6) 1992
Age	28
Age Units	YEARS
Age (Derived)	28
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 02:06:05

Generated On: 09 Jun 2021 17:41:44

Date of Informed Consent (<i>dd MMM yyyy</i>)	09 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 type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 02:06:05

Generated On: 09 Jun 2021 17:41:44

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 02:06:05

Generated On: 09 Jun 2021 17:41:44

Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	09 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:34 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 15:34
Height (<i>xxx.x</i>)	171 cm
Weight (<i>xxx.x</i>)	70 kg
BMI (<i>xxx.x</i>)	23.93899 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) 13 Feb 2021 02:06:05

Generated On: 09 Jun 2021 17:41:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 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) 13 Feb 2021 02:06:05

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Date of assessment (*dd MMM yyyy*) 09 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) 13 Feb 2021 02:06:05

Generated On: 09 Jun 2021 17:41:44

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 09 SEP 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:06:19

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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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Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:06:19

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	True
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) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

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

What was the participant's randomization number? 112949

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) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

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)	09 SEP 2020
Time of assessment (00:00-23:59)	15:34 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 15:34
Temperature (xxx.x)	98.4 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)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

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)	09 SEP 2020
Time of assessment (00:00-23:59)	17:05 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 17:05
Temperature (xxx.x)	97.7 F
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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

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) 06 Apr 2021 22:56:15

Generated On: 09 Jun 2021 17:41:44

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) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 16:34 (24 HR)

Treatment Date and Time (derived) 09 SEP 2020 16:34

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) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 SEP 2020
Collection time (00:00-23:59)	16:22 (24 HR)
Collection date and time (derived)	09 SEP 2020 16:22

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

Collection date (dd MMM yyyy)			09 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:25	09 SEP 2020 16:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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 17:00

PC Open Date & Time

09 SEP 2020 16:54

PC Close Date & Time

09 SEP 2020 19:24

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐
No ☒

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

PC Time Stamp	09 SEP 2020 21:38
PC Open Date & Time	09 SEP 2020 20:19
PC Close Date & Time	10 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:44

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

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

10 SEP 2020 21:14

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 23:11

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:44

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

97.7 °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

12 SEP 2020 21:33

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:44

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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 21:32

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 07:43

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 06:01

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

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

09 SEP 2020 17:04

PC Open Date & Time

09 SEP 2020 16:54

PC Close Date & Time

09 SEP 2020 19:24

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 21:39

PC Open Date & Time

09 SEP 2020 20:19

PC Close Date & Time

10 SEP 2020 11:59

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:44

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

10 SEP 2020 21:15

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:44

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

11 SEP 2020 23:11

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:44

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

12 SEP 2020 21:32

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:44

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

13 SEP 2020 21:30

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:44

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

15 SEP 2020 07:42

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:44

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

16 SEP 2020 06:01

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

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 ☐

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 17:04
PC Open Date & Time	09 SEP 2020 16:54
PC Close Date & Time	09 SEP 2020 19:24

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

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 ☐

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 21:39
PC Open Date & Time	09 SEP 2020 20:19
PC Close Date & Time	10 SEP 2020 11:59

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

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 ☒

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 21:15
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

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 ☒

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

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

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

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 ☒

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 21:32
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

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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EAB) (1725)

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 21:30
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

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

52 of 1829

EAB) (1725)

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 07:42
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

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 ☒

PRODUCTION RELEASE (v12.003

54 of 1829

EAB) (1725)

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 06:02
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3462421

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:06:05

Generated On: 09 Jun 2021 17:41:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462421

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:06:05

Generated On: 09 Jun 2021 17:41:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462421

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:06:05

Generated On: 09 Jun 2021 17:41:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462421

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:06:05

Generated On: 09 Jun 2021 17:41:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462421

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:06:05

Generated On: 09 Jun 2021 17:41:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462421

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:06:05

Generated On: 09 Jun 2021 17:41:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462421

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 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

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

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)	07 OCT 2020
Time of assessment (00:00-23:59)	15:27 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 15:27
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 OCT 2020
Time of assessment (00:00-23:59)	16:42 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 16:42
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3462421

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

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.

US3462421

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	07 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)	

US3462421

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 07 OCT 2020

What was the treatment time? (00:00-23:59) 16:10 (24 HR)

Treatment Date and Time (derived) 07 OCT 2020 16:10

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

US3462421

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 OCT 2020
Collection time (00:00-23:59)	16:01 (24 HR)
Collection date and time (derived)	07 OCT 2020 16:01

US3462421

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

Collection date (dd MMM yyyy)			07 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:03	07 OCT 2020 16:03
Nasopharyngeal Swab 2	No		

US3462421

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 16:46

PC Open Date & Time

07 OCT 2020 16:30

PC Close Date & Time

07 OCT 2020 19:00

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	07 OCT 2020 21:24
PC Open Date & Time	07 OCT 2020 19:55
PC Close Date & Time	08 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 07:28

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 08:18

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:44

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 ☒

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 09:53

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:44

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 21:33

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:44

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

97.7 °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

13 OCT 2020 05:38

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:44

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

14 OCT 2020 08:45

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

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

07 OCT 2020 16:46

PC Open Date & Time

07 OCT 2020 16:30

PC Close Date & Time

07 OCT 2020 19:00

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 21:24

PC Open Date & Time

07 OCT 2020 19:55

PC Close Date & Time

08 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:44

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

09 OCT 2020 07:28

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:44

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

10 OCT 2020 08:18

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:44

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

11 OCT 2020 09:53

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:44

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

11 OCT 2020 21:33

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:44

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

13 OCT 2020 05:37

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:44

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

14 OCT 2020 08:44

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

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 ☐

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 16:47
PC Open Date & Time	07 OCT 2020 16:30
PC Close Date & Time	07 OCT 2020 19:00

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

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 ☐

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 21:24
PC Open Date & Time	07 OCT 2020 19:55
PC Close Date & Time	08 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 07:28
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

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 ☒

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 08:19
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

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 ☒

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EAB) (1725)

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 09:53
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 21:34
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

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

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EAB) (1725)

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 05:37
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 08:44
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3462421

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:06:05

Generated On: 09 Jun 2021 17:41:44

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

US3462421

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:06:05

Generated On: 09 Jun 2021 17:41:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462421

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:06:05

Generated On: 09 Jun 2021 17:41:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462421

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:06:05

Generated On: 09 Jun 2021 17:41:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462421

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:06:05

Generated On: 09 Jun 2021 17:41:44

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3462421

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:06:05

Generated On: 09 Jun 2021 17:41:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462421

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:06:20

Generated On: 09 Jun 2021 17:41:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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

US3462421

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:06:20

Generated On: 09 Jun 2021 17:41:44

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3462421

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:06:20

Generated On: 09 Jun 2021 17:41:44

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.

US3462421

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:06:20

Generated On: 09 Jun 2021 17:41:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 NOV 2020
Collection time (00:00-23:59)	15:35 (24 HR)
Collection date and time (derived)	04 NOV 2020 15:35

US3462421

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:06:19

Generated On: 09 Jun 2021 17:41:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462421

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 12:00:40
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3462421

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 07:35:44

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	23 NOV 2020 05:34:38
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 08:01:57
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 06:22:41

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 06:44:00
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 23:05:45

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 14:43:19

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 16:58:35

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 06:03:35

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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 05:05:38

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	22 JAN 2021 05:49:07
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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	29 JAN 2021 07:00:47
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 05:36:58

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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 05:36:24

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 06:53:57
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

01 MAR 2021 18:22:58

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 13:35:28

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 05:16:07

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 MAR 2021 12:00:19
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 MAR 2021 06:54:47
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 05:43:32

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 08:42:38

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 05:58:53

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

24 APR 2021 15:11:45

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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 07:53:20

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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="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°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="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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2021 00:01
Patient Cloud Close Date & Time	29 JUN 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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="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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2021 00:01
Patient Cloud Close Date & Time	14 SEP 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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 <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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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="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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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 <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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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 <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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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="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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	28 DEC 2021 23:59
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US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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 <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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 FEB 2022 00:01
Patient Cloud Close Date & Time	22 FEB 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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 <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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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 ☐

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 APR 2022 00:01
Patient Cloud Close Date & Time	12 APR 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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="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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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 <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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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 <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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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="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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3462421

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:41:44

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 18:23:13

US3462421

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:13:10

Generated On: 09 Jun 2021 17:41:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462421

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:13:10

Generated On: 09 Jun 2021 17:41:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462421

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:13:10

Generated On: 09 Jun 2021 17:41:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462421

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:13:10

Generated On: 09 Jun 2021 17:41:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462421

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:13:10

Generated On: 09 Jun 2021 17:41:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462421

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:13:10

Generated On: 09 Jun 2021 17:41:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462421

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:13:10

Generated On: 09 Jun 2021 17:41:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462421

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:13:10

Generated On: 09 Jun 2021 17:41:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462421

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

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

Visit date (dd MMM yyyy)	23 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3462421

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3462421

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

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.

US3462421

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 MAR 2021
Collection time (00:00-23:59)	09:10 (24 HR)
Collection date and time (derived)	23 MAR 2021 09:10

US3462421

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462421

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

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

US3462421

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3462421

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:41:44

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"/>

US3462421

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:41:44

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3462421

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:46:57

Generated On: 09 Jun 2021 17:41:44

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

Visit date (dd MMM yyyy)	13 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3462421

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

Date of updated informed consent (<i>dd MMM yyyy</i>)	13 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	13 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3462421

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 20:46:57

Generated On: 09 Jun 2021 17:41:44

Height	171 cm
Weight	70 kg
BMI (xxx.x)	23.93899

US3462421

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:46:57

Generated On: 09 Jun 2021 17:41:44

Height	171 cm
Weight	70 kg
BMI (xxx.x)	23.93899
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)	13 JAN 2021
Time of assessment (00:00-23:59)	04:55 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 04:55
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3462421

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:46:57

Generated On: 09 Jun 2021 17:41:44

Height	171 cm
Weight	70 kg
BMI (xxx.x)	23.93899
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)	13 JAN 2021
Time of assessment (00:00-23:59)	17:56 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 17:56
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3462421

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:46:57

Generated On: 09 Jun 2021 17:41:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 JAN 2021

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

US3462421

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

Form: Pregnancy Test

Data signed: (b) (4) 06 Apr 2021 22:56:15

Generated On: 09 Jun 2021 17:41:44

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 13 JAN 2021

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3462421

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:46:57

Generated On: 09 Jun 2021 17:41:44

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 13 JAN 2021

What was the treatment time? (00:00-23:59) 17:26 (24 HR)

Treatment Date and Time (derived) 13 JAN 2021 17:26

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

What was the frequency of the study treatment dosing? ONCE

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

US3462421

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:46:57

Generated On: 09 Jun 2021 17:41:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00-23:59)	16:50 (24 HR)
Collection date and time (derived)	13 JAN 2021 16:50

US3462421

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 20:46:57

Generated On: 09 Jun 2021 17:41:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00 - 23:59)	16:33
Collection Date and Time (derived)	13 JAN 2021 16:33

US3462421

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:46:57

Generated On: 09 Jun 2021 17:41:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462421

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Apr 2021 21:09:50

Generated On: 09 Jun 2021 17:41:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462421

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

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

US3462421

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

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)	12 FEB 2021
Time of assessment (00:00-23:59)	12:30 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 12:30
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

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)	12 FEB 2021
Time of assessment (00:00-23:59)	14:05 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 14:05
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3462421

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Apr 2021 21:14:13

Generated On: 09 Jun 2021 17:41:44

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.

US3462421

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	12 FEB 2021
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 type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3462421

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 12 FEB 2021

What was the treatment time? (00:00-23:59) 13:35 (24 HR)

Treatment Date and Time (derived) 12 FEB 2021 13:35

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

US3462421

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462421

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3462421

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462421

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3462421

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3462421

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

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.

US3462421

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 18:21:02

Generated On: 09 Jun 2021 17:41:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	23 MAR 2021
Collection time (<i>00:00-23:59</i>)	09:10 (24 HR)
Collection date and time (derived)	23 MAR 2021 09:10

US3462421

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 20:46:57

Generated On: 09 Jun 2021 17:41:44

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 22:56:15

Generated On: 09 Jun 2021 17:41:44

AEID	USA-US093-2021-MRNA-1273-P30 1000004
Adverse event	PREGNANCY ON THE STUDY
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 22:56:15

Generated On: 09 Jun 2021 17:41:44

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

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 22:56:15

Generated On: 09 Jun 2021 17:41:44

SUBJECT IS A 28 YEAR OLD FEMALE WHO COMPLETED OPEN-LABEL VISIT 1 AND RECEIVED FIRST DOSE OF OPEN-LABEL IP ON 13JAN2021. SUBJECT HAD A NEGATIVE PREGNANCY TEST AT THIS VISIT PRIOR TO DOSING. SUBJECT REPORTED THAT HER LAST MENSTRUAL CYCLE PRIOR TO THIS VISIT STARTED ON APPROXIMATELY 16DEC2020. SUBJECT STATED THAT SHE HAS VERY REGULAR CYCLES AND THEREFORE, WHEN SHE HAD NOT STARTED HER NEXT MENSTRUAL CYCLE (EXPECTED TO START ON OR AROUND 16-18JAN2021), SUBJECT PERFORMED AN AT HOME PREGNANCY TEST. TEST WAS CONDUCTED ON 21JAN2021 AND WAS POSITIVE. ON 23JAN2021, SUBJECT REPORTED THAT SHE STARTED BLEEDING AND INITIALLY THOUGHT THAT SHE MIGHT BE STARTING HER NEXT MENSES, HOWEVER, SUBJECT NOTICED THAT SHE HAD CLOTS ALONG WITH HER NORMAL BLEEDING. SUBJECT REPORTED THAT SHE CONTINUED TO BLEED FOR THE NEXT 6 DAYS WITH BLEEDING STOPPING ON

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 22:56:15

Generated On: 09 Jun 2021 17:41:44

29JAN2021. SUBJECT STATED THAT SHE HAS NOT TAKEN ADDITIONAL PREGNANCY TEST, BUT BELIEVES THAT SHE IS NO LONGER PREGNANT. SUBJECT REPORTED MINIMAL SYMPTOMS AND FELT STABLE. ALL DETAILS WERE PROVIDED VIA SUBJECT PHONE CALL WITH SITE ON 02FEB2021 AS SUBJECT HAS NOT YET SEEN A DOCTOR. SUBJECT STATED THAT SHE DOES HAVE A VISIT SCHEDULED FOR LATER THIS WEEK. PI EVALUATED THIS SAE AND DETERMINED THAT SINCE IP CAUSALITY CANNOT BE RULED OUT AND DUE TO TEMPOROL RELATIONSHIP, WE WILL LIST THIS SAE AS RELATED FOR NOW.

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

US3462421

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 22:56:15

Generated On: 09 Jun 2021 17:41:44

AEID	USA-US093-2021-MRNA-1273-P30 1000004
Adverse event	MISCARRIAGE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 22:56:15

Generated On: 09 Jun 2021 17:41:44

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

US3462421

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 22:56:15

Generated On: 09 Jun 2021 17:41:44

SUBJECT IS A 28 YEAR OLD FEMALE WHO COMPLETED OPEN-LABEL VISIT 1 AND RECEIVED FIRST DOSE OF OPEN-LABEL IP ON 13JAN2021. SUBJECT HAD A NEGATIVE PREGNANCY TEST AT THIS VISIT PRIOR TO DOSING. SUBJECT REPORTED THAT HER LAST MENSTRUAL CYCLE PRIOR TO THIS VISIT STARTED ON APPROXIMATELY 16DEC2020. SUBJECT STATED THAT SHE HAS VERY REGULAR CYCLES AND THEREFORE, WHEN SHE HAD NOT STARTED HER NEXT MENSTRUAL CYCLE (EXPECTED TO START ON OR AROUND 16-18JAN2021), SUBJECT PERFORMED AN AT HOME PREGNANCY TEST. TEST WAS CONDUCTED ON 21JAN2021 AND WAS POSITIVE. ON 23JAN2021, SUBJECT REPORTED THAT SHE STARTED BLEEDING AND INITIALLY THOUGHT THAT SHE MIGHT BE STARTING HER NEXT MENSES, HOWEVER, SUBJECT NOTICED THAT SHE HAD CLOTS ALONG WITH HER NORMAL BLEEDING. SUBJECT REPORTED THAT SHE CONTINUED TO BLEED FOR THE NEXT 6 DAYS WITH BLEEDING STOPPING ON

US3462421

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 22:56:15

Generated On: 09 Jun 2021 17:41:44

29JAN2021. SUBJECT STATED THAT SHE HAS NOT TAKEN ADDITIONAL PREGNANCY TEST, BUT BELIEVES THAT SHE IS NO LONGER PREGNANT. SUBJECT REPORTED MINIMAL SYMPTOMS AND FELT STABLE. ALL DETAILS WERE PROVIDED VIA SUBJECT PHONE CALL WITH SITE ON 02FEB2021 AS SUBJECT HAS NOT YET SEEN A DOCTOR. SUBJECT STATED THAT SHE DOES HAVE A VISIT SCHEDULED FOR LATER THIS WEEK. PI EVALUATED THIS SAE AND DETERMINED THAT SINCE IP CAUSALITY CANNOT BE RULED OUT AND DUE TO TEMPOROL RELATIONSHIP, WE WILL LIST THIS SAE AS RELATED FOR NOW.

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

US3462421

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 20:46:57

Generated On: 09 Jun 2021 17:41:44

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

Yes ☐

No ☒

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

US3462421

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:41:44

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3462421

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:41:44

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

US3462421

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:41:44

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 ☐

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 20:46:57

Generated On: 09 Jun 2021 17:41:44

SAEID	USA-US093-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 20:46:57

Generated On: 09 Jun 2021 17:41:44

SAEID	USA-US093-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	03/FEB/2021 19:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3462421 (Prod: Crisor, LLC)

US3462421

Form: Participant Creation

Generated On: 09 Jun 2021 17:41:44

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'US3462421'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 22:29:16

US3462421

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:46:50
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	09 Sep 2020 23:53:55

US3462421

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:46:50
User entered '09 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 22:29:17

US3462421

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

[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 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:46:50
User entered 'Clinic (Clinic)'	Danuel Hamlin (b) (4)	09 Sep 2020 23:53:55

US3462421

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'SCRN'	System	09 Sep 2020 23:53:55

US3462421

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:44

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:47:10
User entered (b) (6) 1992'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 22:29:18

US3462421

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:44

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:47:10
User entered '28'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:17

US3462421

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:44

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'YEARS'	System	09 Sep 2020 23:54:17

US3462421

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:44

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered '28'	System	09 Sep 2020 23:54:35

US3462421

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:44

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:47:10
User entered 'Female (F)'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:17

US3462421

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:44

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:47:10
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:17

US3462421

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:44

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:47:10
User entered 'l'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:17

US3462421

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:44

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:47:10
User entered '0'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:17

US3462421

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:44

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:47:10
User entered '0'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:17

US3462421

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:44

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:47:10
User entered '0'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:17

US3462421

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:44

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:47:10
User entered '0'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:17

US3462421

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:47:10
User entered '0'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:17

US3462421

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:44

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:47:10
User entered empty.	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:17

US3462421

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:44

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:47:10
User entered '0'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:17

US3462421

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:44

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:47:10
User entered '0'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:17

US3462421

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:44

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:47:19
User entered '09 Sep 2020'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:35

US3462421

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'Sep 2020'	System	09 Sep 2020 23:54:35

US3462421

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered '2020'	System	09 Sep 2020 23:54:35

US3462421

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:44

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:47:19
User entered 'Amendment 3 (3)'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:35

US3462421

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:47:19
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:35

US3462421

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:44

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:47:19
User entered empty.	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:35

US3462421

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:44

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:47:19
User entered empty.	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:35

US3462421

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:44

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:47:19
User entered 'No (N)'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:35

US3462421

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:44

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:47:19
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 22:29:17

US3462421

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:44

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'I'	System	09 Sep 2020 23:54:42

US3462421

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:47:26
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:42

US3462421

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:41:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:47:37
User entered 'No (N)'		12 Sep 2020 19:52:02

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:14
User entered 'Yes (Y)'		12 Sep 2020 19:53:00

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:14
User entered '09 Sep 2020'		12 Sep 2020 19:53:00

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:14
User entered '15:34'		12 Sep 2020 19:53:00

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered '09 Sep 2020 15:34'	System	12 Sep 2020 19:53:00

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:14
User entered '171' cm		12 Sep 2020 19:53:00
DataPoint set to visible.	System	09 Sep 2020 23:54:42

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:14
User entered '70' kg		12 Sep 2020 19:53:00
DataPoint set to visible.	System	09 Sep 2020 23:54:42

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered '23.93899'	System	12 Sep 2020 19:53:00
DataPoint set to visible.	System	09 Sep 2020 23:54:42

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'kg/m2'	System	12 Sep 2020 19:53:00
DataPoint set to visible.	System	09 Sep 2020 23:54:42

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:14
User closed query 'Per CDM: Per CCGs pages 15-16, please enter Not Done in the data field of the edc for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP.' (Site from DM).		03 Nov 2020 16:07:19
Query 'Per CDM: Per CCGs pages 15-16, please enter Not Done in the data field of the edc for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP.' answered with 'UPDATED' (Site from DM).		18 Oct 2020 22:43:26
User entered missing code ND - Not Done; reason for change Data Entry Error		18 Oct 2020 22:43:14
User opened query 'Per CDM: Per CCGs pages 15-16, please enter Not Done in the data field of the edc for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP.' (Site from DM).		24 Sep 2020 09:17:06
User entered '98.4' F		12 Sep 2020 19:53:00

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:14
User entered empty; reason for change Data Entry Error		18 Oct 2020 22:43:14
User entered 'Other (Other)'		12 Sep 2020 19:53:00

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:14
User entered empty; reason for change Data Entry Error		18 Oct 2020 22:43:14
User entered 'Tympanic'		12 Sep 2020 19:53:00

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:14
User entered missing code ND - Not Done; reason for change Data Entry Error		18 Oct 2020 22:43:14
User entered '66'		12 Sep 2020 19:53:00

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'bpm'	System	12 Sep 2020 19:53:00

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:14
User entered missing code ND - Not Done; reason for change Data Entry Error		18 Oct 2020 22:43:14
User entered '16'		12 Sep 2020 19:53:00

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'breaths/min'	System	12 Sep 2020 19:53:00

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:14
User entered missing code ND - Not Done; reason for change Data Entry Error		18 Oct 2020 22:43:14
User entered '112'		12 Sep 2020 19:53:00

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'mmHg'	System	12 Sep 2020 19:53:00

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:14
User entered missing code ND - Not Done; reason for change Data Entry Error		18 Oct 2020 22:43:14
User entered '72'		12 Sep 2020 19:53:00

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'mmHg'	System	12 Sep 2020 19:53:00

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26

US3462421

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26

US3462421

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:19
User entered 'Yes (Y)'		12 Sep 2020 19:53:12

US3462421

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:19
User entered '09 Sep 2020'		12 Sep 2020 19:53:12

US3462421

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:33
User entered '09 Sep 2020'		12 Sep 2020 19:53:36

US3462421

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:33
User entered 'Yes (Y)'		12 Sep 2020 19:53:36

US3462421

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:33
User entered empty.		12 Sep 2020 19:53:36

US3462421

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:44

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:33
User entered empty.		12 Sep 2020 19:53:36

US3462421

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:33
User entered empty.		12 Sep 2020 19:53:36

US3462421

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:44

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:33
User entered '0'		12 Sep 2020 19:53:36

US3462421

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:33
User entered empty.		12 Sep 2020 19:53:36

US3462421

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:44

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:33
User entered '0'		12 Sep 2020 19:53:36

US3462421

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:41
User entered 'Yes (Y)'		26 Sep 2020 20:23:45

US3462421

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:41
User entered '09 Sep 2020'		26 Sep 2020 20:23:45

US3462421

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:41
User entered 'Urine (URINE)'		26 Sep 2020 20:23:45

US3462421

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:41
User entered 'Negative (NEGATIVE)'		26 Sep 2020 20:23:45

US3462421

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:41
User entered 'No (N)'		26 Sep 2020 20:23:45

US3462421

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:41
User entered empty.		26 Sep 2020 20:23:45

US3462421

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:41
User entered empty.		26 Sep 2020 20:23:45

US3462421

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered empty.	System	26 Sep 2020 20:23:45

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

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 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered 'Yes (Y)'		12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

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 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered 'No (N)'		12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

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 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered 'No (N)'		12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

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 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered 'No (N)'		12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

[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 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered 'No (N)'		12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

[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 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered 'No (N)'		12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

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 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered 'No (N)'		12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

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 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered 'No (N)'		12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

[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 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered 'No (N)'		12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

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 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered 'No (N)'		12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

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 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered 'No (N)'		12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered 'No (N)'		12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered empty.		12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
User entered '0'	(b) (4), (b) (6)	12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered '0'		12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

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 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered '0'		12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

[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 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered '0'		12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

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 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered 'I'		12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered '0'		12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
User entered '0'	(b) (4), (b) (6)	12 Sep 2020 19:54:41

US3462421

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:48:50
User entered empty.		12 Sep 2020 19:54:41

US3462421

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:49:13
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:56

US3462421

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:49:13
User entered '09 Sep 2020'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:56

US3462421

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:49:13
User entered 'Clinic (Clinic)'	Danuel Hamlin (b) (4)	09 Sep 2020 23:54:56

US3462421

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'VISIT1'	System	09 Sep 2020 23:54:56

US3462421

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:49:23
User entered '09 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 23:14:34

US3462421

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:49:23
User entered '112949'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 23:14:34

US3462421

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:49:23
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 23:14:34

US3462421

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:44

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)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:49:23
User entered 'No (N)'		12 Sep 2020 19:57:01

US3462421

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:44

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)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:49:23
User entered 'No (N)'		12 Sep 2020 19:57:01

US3462421

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:49:23
User entered 'No (N)'		12 Sep 2020 19:57:01

US3462421

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:44

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:49:23
User entered 'No (N)'		12 Sep 2020 19:57:01

US3462421

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:44

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:49:23
User entered 'No (N)'		12 Sep 2020 19:57:01

US3462421

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:44

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:49:23
User entered 'No (N)'		26 Sep 2020 20:23:54
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:54:29
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:54:28

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User closed query 'Per CDM: Per CCGs pages 15-16, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).		20 Oct 2020 20:39:02
Query 'Per CDM: Per CCGs pages 15-16, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'UPDATED' (Site from DM).		18 Oct 2020 22:45:24
User entered missing code ND - Not Done; reason for change Data Entry Error		18 Oct 2020 22:45:15
User opened query 'Per CDM: Per CCGs pages 15-16, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).		24 Sep 2020 09:16:50
User entered '171' cm		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User closed query 'Per CDM: Please also record the WEIGHT as Not Done.' (Site from DM).		02 Nov 2020 16:17:02
Query 'Per CDM: Please also record the WEIGHT as Not Done.' answered with 'UPDATED' (Site from DM).		02 Nov 2020 03:55:56
User entered missing code ND - Not Done; reason for change Data Entry Error		02 Nov 2020 03:55:39
User opened query 'Per CDM: Please also record the WEIGHT as Not Done.' (Site from DM).		23 Oct 2020 08:47:52
User entered empty; reason for change Data Entry Error		18 Oct 2020 22:45:15
User entered '70' kg		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User closed query 'Per CDM: Per CCGs pages 15-16, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).		20 Oct 2020 20:39:02
Query 'Per CDM: Per CCGs pages 15-16, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'UPDATED' (Site from DM).		18 Oct 2020 22:45:24
User entered missing code ND - Not Done; reason for change Data Entry Error		18 Oct 2020 22:45:15
User opened query 'Per CDM: Per CCGs pages 15-16, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).		24 Sep 2020 09:16:50
User entered '171' cm		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User closed query 'Per CDM: Please also record the WEIGHT as Not Done.' (Site from DM).		02 Nov 2020 16:17:02
Query 'Per CDM: Please also record the WEIGHT as Not Done.' answered with 'UPDATED' (Site from DM).		02 Nov 2020 03:55:56
User entered missing code ND - Not Done; reason for change Data Entry Error		02 Nov 2020 03:55:39
User opened query 'Per CDM: Please also record the WEIGHT as Not Done.' (Site from DM).		23 Oct 2020 08:47:52
User entered empty; reason for change Data Entry Error		18 Oct 2020 22:45:15
User entered '70' kg		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User accepted default value 'Pre-Dose (PREDOSE)'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered 'Yes (Y)'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered '09 Sep 2020'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered '15:34'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered '09 Sep 2020 15:34'	System	12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered '98.4' F		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered 'Other (Other)'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered 'Tympanic'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered '66'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'bpm'	System	12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered '16'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'breaths/min'	System	12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered '112'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'mmHg'	System	12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered '72'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'mmHg'	System	12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User closed query 'Per CDM: Per CCGs pages 15-16, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).		20 Oct 2020 20:39:02
Query 'Per CDM: Per CCGs pages 15-16, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'UPDATED' (Site from DM).		18 Oct 2020 22:45:24
User entered missing code ND - Not Done; reason for change Data Entry Error		18 Oct 2020 22:45:15
User opened query 'Per CDM: Per CCGs pages 15-16, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).		24 Sep 2020 09:16:50
User entered '171' cm		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User closed query 'Per CDM: Please also record the WEIGHT as Not Done.' (Site from DM).		02 Nov 2020 16:17:02
Query 'Per CDM: Please also record the WEIGHT as Not Done.' answered with 'UPDATED' (Site from DM).		02 Nov 2020 03:55:56
User entered missing code ND - Not Done; reason for change Data Entry Error		02 Nov 2020 03:55:39
User opened query 'Per CDM: Please also record the WEIGHT as Not Done.' (Site from DM).		23 Oct 2020 08:47:52
User entered empty; reason for change Data Entry Error		18 Oct 2020 22:45:15
User entered '70' kg		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User accepted default value 'Post-Dose (POSTDOSE)'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered 'Yes (Y)'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered '09 Sep 2020'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered '17:05'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered '09 Sep 2020 17:05'	System	12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered '97.7' F		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered 'Other (Other)'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered 'Tympanic'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered '64'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'bpm'	System	12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered '16'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'breaths/min'	System	12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered '102'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'mmHg'	System	12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:39
User entered '68'		12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'mmHg'	System	12 Sep 2020 19:58:47

US3462421

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:46
User entered 'No (N)' reason for change: Data Entry Error		02 Nov 2020 03:56:45
User entered 'Yes (Y)'		12 Sep 2020 19:59:17

US3462421

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:50:46
User entered empty; reason for change Data Entry Error		02 Nov 2020 03:56:45
User entered '09 Sep 2020'		12 Sep 2020 19:59:17

US3462421

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User closed query 'Per EDC guidelines, this should be noted as NO as this is captured on Screening visit in EDC. Please update accordingly.' (Site from CRA).		14 Apr 2021 17:31:31
DataPoint Verified.		14 Apr 2021 17:31:29
User signature succeeded.		06 Apr 2021 22:56:16
Query 'Per EDC guidelines, this should be noted as NO as this is captured on Screening visit in EDC. Please update accordingly.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 20:51:33
User entered 'No (N)' reason for change: Data Entry Error		06 Apr 2021 20:51:20
User opened query 'Per EDC guidelines, this should be noted as NO as this is captured on Screening visit in EDC. Please update accordingly.' (Site from CRA).		16 Dec 2020 20:51:09
User entered 'Yes (Y)'		12 Sep 2020 19:59:45

US3462421

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
DataPoint Verified.		14 Apr 2021 17:31:29
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:51:20
User entered '09 Sep 2020'		12 Sep 2020 19:59:45

US3462421

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
DataPoint Verified.		14 Apr 2021 17:31:29
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:51:20
User entered 'Urine (URINE)'		12 Sep 2020 19:59:45

US3462421

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
DataPoint Verified.		14 Apr 2021 17:31:29
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:51:20
User entered 'Negative (NEGATIVE)'		12 Sep 2020 19:59:45

US3462421

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
DataPoint Verified.		14 Apr 2021 17:31:29
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	12 Sep 2020 19:59:45

US3462421

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
DataPoint Verified.		14 Apr 2021 17:31:29
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Sep 2020 19:59:45

US3462421

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
DataPoint Verified.		14 Apr 2021 17:31:29
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Sep 2020 19:59:45

US3462421

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered empty.	System	12 Sep 2020 19:59:45

US3462421

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:51:33
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	09 Sep 2020 23:55:23

US3462421

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:51:33
User entered empty.	Danuel Hamlin (b) (4)	09 Sep 2020 23:55:23

US3462421

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:51:33
User entered empty.	Danuel Hamlin (b) (4)	09 Sep 2020 23:55:23

US3462421

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 23:55:23

US3462421

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:51:33
User entered '09 Sep 2020'	Danuel Hamlin (b) (4)	09 Sep 2020 23:55:23

US3462421

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:51:33
User entered '16:34'	Danuel Hamlin (b) (4)	09 Sep 2020 23:55:23

US3462421

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered '09 Sep 2020 16:34'	System	09 Sep 2020 23:55:23

US3462421

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:51:33
User entered 'Left Arm (LEFT ARM)'	Danuel Hamlin (b) (4)	09 Sep 2020 23:55:23

US3462421

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
DataPoint Verified.		16 Dec 2020 20:51:33
User entered 'ONCE'	System	09 Sep 2020 23:55:23

US3462421

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 23:55:23

US3462421

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:51:42
User entered 'Yes (Y)'		12 Sep 2020 20:00:08

US3462421

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:51:42
User entered '09 Sep 2020'		12 Sep 2020 20:00:08

US3462421

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:51:42
User entered '16:22'		12 Sep 2020 20:00:08

US3462421

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered '09 Sep 2020 16:22'	System	12 Sep 2020 20:00:08

US3462421

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:41:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:51:48
User entered '09 Sep 2020'		12 Sep 2020 20:00:25

US3462421

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		12 Sep 2020 20:00:25

US3462421

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:51:48
User entered 'Yes (Y)'		12 Sep 2020 20:00:25

US3462421

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:51:48
User entered '16:25'		12 Sep 2020 20:00:25

US3462421

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered '09 Sep 2020 16:25'	System	12 Sep 2020 20:00:25

US3462421

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		12 Sep 2020 20:00:25

US3462421

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:51:48
User entered 'No (N)' reason for change: Data Entry Error		13 Oct 2020 04:43:08
User entered 'Yes (Y)'		12 Sep 2020 20:00:25

US3462421

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:51:48
User closed query 'Was sample collected is No, however Collection time is provided. Please correct.' (Site from System).	System	13 Oct 2020 04:43:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 04:43:16
User opened query 'Was sample collected is No, however Collection time is provided. Please correct.' (Site from System).	System	13 Oct 2020 04:43:08
User entered '16:25'	(b) (4), (b) (6)	12 Sep 2020 20:00:25

US3462421

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:44

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered empty.	System	13 Oct 2020 04:43:16
User entered '09 Sep 2020 16:25'	System	12 Sep 2020 20:00:25

US3462421

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:51:54
User entered 'Yes (Y)'		12 Sep 2020 20:00:48

US3462421

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'I'	System	12 Sep 2020 20:00:48

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T17:00:31', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '78b7770d-3c50-438a-ad3b-da37da683810' User entered 'Yes (Y)'	System	10 Sep 2020 00:00:50
	System	10 Sep 2020 00:00:50

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T17:00:37', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '78b7770d-3c50-438a-ad3b-da37da683810' User entered '97.7'	System	10 Sep 2020 00:00:50
	System	10 Sep 2020 00:00:50

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T17:00:42', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '78b7770d-3c50-438a-ad3b-da37da683810'	System	10 Sep 2020 00:00:50
User entered 'No (N)'	System	10 Sep 2020 00:00:50

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T17:00:45', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '78b7770d-3c50-438a-ad3b-da37da683810'	System	10 Sep 2020 00:00:50
User entered '09 Sep 2020 17:00'	System	10 Sep 2020 00:00:50

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '09 Sep 2020 16:54'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '09 Sep 2020 19:24'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T21:37:08', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '016658d2-bcd7-4a73-88de-03878a6df05b' User entered 'Yes (Y)'	System	10 Sep 2020 04:38:38
	System	10 Sep 2020 04:38:38

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T21:38:26', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '016658d2-bcd7-4a73-88de-03878a6df05b' User entered '97.5'	System	10 Sep 2020 04:38:38
	System	10 Sep 2020 04:38:38

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T21:38:29', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '016658d2-bcd7-4a73-88de-03878a6df05b' User entered 'No (N)'	System	10 Sep 2020 04:38:38
	System	10 Sep 2020 04:38:38

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T21:38:35', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '016658d2-bcd7-4a73-88de-03878a6df05b' User entered '09 Sep 2020 21:38'	System	10 Sep 2020 04:38:38
	System	10 Sep 2020 04:38:38

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '09 Sep 2020 20:19'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 2'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-10T21:12:49', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '722b245f-712a-4e4e-8780-d15b9b2278e1' User entered 'Yes (Y)'	System	11 Sep 2020 04:14:36
	System	11 Sep 2020 04:14:36

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-10T21:14:14', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '722b245f-712a-4e4e-8780-d15b9b2278e1' User entered '96.8'	System	11 Sep 2020 04:14:36
	System	11 Sep 2020 04:14:36

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-10T21:14:17', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '722b245f-712a-4e4e-8780-d15b9b2278e1' User entered 'No (N)'	System	11 Sep 2020 04:14:36
	System	11 Sep 2020 04:14:36

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-10T21:14:32', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '722b245f-712a-4e4e-8780-d15b9b2278e1' User entered '10 Sep 2020 21:14'	System	11 Sep 2020 04:14:36
	System	11 Sep 2020 04:14:36

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 3'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-11T23:11:28', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'c286dc87-c153-4819-b35d-1ec3c6e386dc' User entered 'Yes (Y)'	System	12 Sep 2020 06:11:47
	System	12 Sep 2020 06:11:47

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-11T23:11:34', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'c286dc87-c153-4819-b35d-1ec3c6e386dc' User entered '97.6'	System	12 Sep 2020 06:11:47
	System	12 Sep 2020 06:11:47

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-11T23:11:36', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'c286dc87-c153-4819-b35d-1ec3c6e386dc' User entered 'No (N)'	System	12 Sep 2020 06:11:47
	System	12 Sep 2020 06:11:47

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-11T23:11:44', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'c286dc87-c153-4819-b35d-1ec3c6e386dc' User entered '11 Sep 2020 23:11'	System	12 Sep 2020 06:11:47
	System	12 Sep 2020 06:11:47

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 4'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-12T21:32:53', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '42fb5f3b-e2e3-491f-842e-68febe33cccf' User entered 'Yes (Y)'	System	13 Sep 2020 04:33:06
	System	13 Sep 2020 04:33:06

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-12T21:32:58', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '42fb5f3b-e2e3-491f-842e-68febe33cccf' User entered '97.7'	System	13 Sep 2020 04:33:06
	System	13 Sep 2020 04:33:06

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-12T21:33:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '42fb5f3b-e2e3-491f-842e-68febe33cccf' User entered 'No (N)'	System	13 Sep 2020 04:33:06
	System	13 Sep 2020 04:33:06

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-12T21:33:04', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '42fb5f3b-e2e3-491f-842e-68febe33cccf'	System	13 Sep 2020 04:33:06
User entered '12 Sep 2020 21:33'	System	13 Sep 2020 04:33:06

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 5'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-13T21:30:57', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '6cc2954c-c5cb-470f-a361-08d6cb85cf07'	System	14 Sep 2020 04:32:18
User entered 'Yes (Y)'	System	14 Sep 2020 04:32:18

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-13T21:32:09', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '6cc2954c-c5cb-470f-a361-08d6cb85cf07'	System	14 Sep 2020 04:32:18
User entered '96.3'	System	14 Sep 2020 04:32:18

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-13T21:32:11', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '6cc2954c-c5cb-470f-a361-08d6cb85cf07'	System	14 Sep 2020 04:32:18
User entered 'No (N)'	System	14 Sep 2020 04:32:18

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-13T21:32:14', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '6cc2954c-c5cb-470f-a361-08d6cb85cf07'	System	14 Sep 2020 04:32:18
User entered '13 Sep 2020 21:32'	System	14 Sep 2020 04:32:18

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 6'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-15T07:42:51', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '433db952-3e1a-4242-90e9-86dfd91ed472'	System	15 Sep 2020 14:43:27
User entered 'Yes (Y)'	System	15 Sep 2020 14:43:27

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-15T07:43:17', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '433db952-3e1a-4242-90e9-86dfd91ed472'	System	15 Sep 2020 14:43:27
User entered '97.6'	System	15 Sep 2020 14:43:27

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-15T07:43:21', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '433db952-3e1a-4242-90e9-86dfd91ed472'	System	15 Sep 2020 14:43:27
User entered 'No (N)'	System	15 Sep 2020 14:43:27

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-15T07:43:23', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '433db952-3e1a-4242-90e9-86dfd91ed472' User entered '15 Sep 2020 07:43'	System	15 Sep 2020 14:43:27
	System	15 Sep 2020 14:43:27

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 7'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-16T06:01:36', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '033ae39b-d528-4932-8e56-6192e17e5b41'	System	16 Sep 2020 13:01:53
User entered 'Yes (Y)'	System	16 Sep 2020 13:01:53

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-16T06:01:39', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '033ae39b-d528-4932-8e56-6192e17e5b41' User entered '96.8'	System	16 Sep 2020 13:01:53
	System	16 Sep 2020 13:01:53

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-16T06:01:46', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '033ae39b-d528-4932-8e56-6192e17e5b41'	System	16 Sep 2020 13:01:53
User entered 'No (N)'	System	16 Sep 2020 13:01:53

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-16T06:01:48', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '033ae39b-d528-4932-8e56-6192e17e5b41'	System	16 Sep 2020 13:01:53
User entered '16 Sep 2020 06:01'	System	16 Sep 2020 13:01:53

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T17:03:45', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '440af7c8-8c18-47ca-8bb5-623bdefd78b3' User entered 'None (1)'	System	10 Sep 2020 00:04:08
	System	10 Sep 2020 00:04:08

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T17:03:48', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '440af7c8-8c18-47ca-8bb5-623bdefd78b3'	System	10 Sep 2020 00:04:08
User entered 'No (N)'	System	10 Sep 2020 00:04:08

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T17:03:51', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '440af7c8-8c18-47ca-8bb5-623bdefd78b3' User entered 'No (N)'	System	10 Sep 2020 00:04:08
	System	10 Sep 2020 00:04:08

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T17:03:59', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '440af7c8-8c18-47ca-8bb5-623bdefd78b3' User entered 'None (1)'	System	10 Sep 2020 00:04:08
	System	10 Sep 2020 00:04:08

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T17:04:01', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '440af7c8-8c18-47ca-8bb5-623bdefd78b3'	System	10 Sep 2020 00:04:08
User entered '09 Sep 2020 17:04'	System	10 Sep 2020 00:04:08

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '09 Sep 2020 16:54'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '09 Sep 2020 19:24'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T21:38:41', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'eb08e369-321c-4bfb-a33f-57d328001a5b' User entered 'None (1)'	System	10 Sep 2020 04:39:17
	System	10 Sep 2020 04:39:17

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T21:38:52', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'eb08e369-321c-4bfb-a33f-57d328001a5b' User entered 'No (N)'	System	10 Sep 2020 04:39:17
	System	10 Sep 2020 04:39:17

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T21:39:05', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'eb08e369-321c-4bfb-a33f-57d328001a5b' User entered 'No (N)'	System	10 Sep 2020 04:39:17
	System	10 Sep 2020 04:39:17

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T21:39:11', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'eb08e369-321c-4bfb-a33f-57d328001a5b' User entered 'None (1)'	System	10 Sep 2020 04:39:17
	System	10 Sep 2020 04:39:17

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T21:39:15', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'eb08e369-321c-4bfb-a33f-57d328001a5b' User entered '09 Sep 2020 21:39'	System	10 Sep 2020 04:39:17
	System	10 Sep 2020 04:39:17

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '09 Sep 2020 20:19'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 2'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-10T21:14:45', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '10b6414c-4c40-4709-917b-43178a0c1504' User entered 'None (1)'	System	11 Sep 2020 04:15:11
	System	11 Sep 2020 04:15:11

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-10T21:14:50', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '10b6414c-4c40-4709-917b-43178a0c1504'	System	11 Sep 2020 04:15:11
User entered 'No (N)'	System	11 Sep 2020 04:15:11

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-10T21:14:52', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '10b6414c-4c40-4709-917b-43178a0c1504'	System	11 Sep 2020 04:15:11
User entered 'No (N)'	System	11 Sep 2020 04:15:11

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-10T21:14:55', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '10b6414c-4c40-4709-917b-43178a0c1504' User entered 'None (1)'	System	11 Sep 2020 04:15:11
	System	11 Sep 2020 04:15:11

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-10T21:15:03', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '10b6414c-4c40-4709-917b-43178a0c1504'	System	11 Sep 2020 04:15:11
User entered '10 Sep 2020 21:15'	System	11 Sep 2020 04:15:11

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 3'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-11T23:11:47', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1abdbcb7-2e3f-48d8-992f-bfb8aad5af89' User entered 'None (1)'	System	12 Sep 2020 06:11:57
	System	12 Sep 2020 06:11:57

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-11T23:11:49', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1abdbcb7-2e3f-48d8-992f-bfb8aad5af89'	System	12 Sep 2020 06:11:57
User entered 'No (N)'	System	12 Sep 2020 06:11:57

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-11T23:11:51', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1abdbcb7-2e3f-48d8-992f-bfb8aad5af89'	System	12 Sep 2020 06:11:57
User entered 'No (N)'	System	12 Sep 2020 06:11:57

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-11T23:11:53', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1abdbcb7-2e3f-48d8-992f-bfb8aad5af89' User entered 'None (1)'	System	12 Sep 2020 06:11:57
	System	12 Sep 2020 06:11:57

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-11T23:11:55', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1abdbcb7-2e3f-48d8-992f-bfb8aad5af89'	System	12 Sep 2020 06:11:57
User entered '11 Sep 2020 23:11'	System	12 Sep 2020 06:11:57

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 4'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-12T21:32:36', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1abb2385-f0f8-4c45-9485-71937378f287' User entered 'None (1)'	System	13 Sep 2020 04:32:50
	System	13 Sep 2020 04:32:50

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-12T21:32:39', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1abb2385-f0f8-4c45-9485-71937378f287'	System	13 Sep 2020 04:32:50
User entered 'No (N)'	System	13 Sep 2020 04:32:50

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-12T21:32:42', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1abb2385-f0f8-4c45-9485-71937378f287' User entered 'No (N)'	System	13 Sep 2020 04:32:50
	System	13 Sep 2020 04:32:50

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-12T21:32:46', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1abb2385-f0f8-4c45-9485-71937378f287' User entered 'None (1)'	System	13 Sep 2020 04:32:50
	System	13 Sep 2020 04:32:50

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-12T21:32:48', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1abb2385-f0f8-4c45-9485-71937378f287'	System	13 Sep 2020 04:32:50
User entered '12 Sep 2020 21:32'	System	13 Sep 2020 04:32:50

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 5'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-13T21:30:33', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '0ef960f7-19ca-42bb-989a-cc6a1b2d106a' User entered 'None (1)'	System	14 Sep 2020 04:30:47
	System	14 Sep 2020 04:30:47

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-13T21:30:36', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '0ef960f7-19ca-42bb-989a-cc6a1b2d106a' User entered 'No (N)'	System	14 Sep 2020 04:30:47
	System	14 Sep 2020 04:30:47

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-13T21:30:38', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '0ef960f7-19ca-42bb-989a-cc6a1b2d106a'	System	14 Sep 2020 04:30:47
User entered 'No (N)'	System	14 Sep 2020 04:30:47

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-13T21:30:40', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '0ef960f7-19ca-42bb-989a-cc6a1b2d106a' User entered 'None (1)'	System	14 Sep 2020 04:30:47
	System	14 Sep 2020 04:30:47

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-13T21:30:44', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '0ef960f7-19ca-42bb-989a-cc6a1b2d106a' User entered '13 Sep 2020 21:30'	System	14 Sep 2020 04:30:47
	System	14 Sep 2020 04:30:47

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 6'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-15T07:42:39', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'a02816e8-54d3-4fab-ae4c-632a88747c06' User entered 'None (1)'	System	15 Sep 2020 14:42:50
	System	15 Sep 2020 14:42:50

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-15T07:42:41', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'a02816e8-54d3-4fab-ae4c-632a88747c06'	System	15 Sep 2020 14:42:50
User entered 'No (N)'	System	15 Sep 2020 14:42:50

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-15T07:42:43', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'a02816e8-54d3-4fab-ae4c-632a88747c06'	System	15 Sep 2020 14:42:50
User entered 'No (N)'	System	15 Sep 2020 14:42:50

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-15T07:42:45', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'a02816e8-54d3-4fab-ae4c-632a88747c06' User entered 'None (1)'	System	15 Sep 2020 14:42:50
	System	15 Sep 2020 14:42:50

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-15T07:42:47', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'a02816e8-54d3-4fab-ae4c-632a88747c06' User entered '15 Sep 2020 07:42'	System	15 Sep 2020 14:42:50
	System	15 Sep 2020 14:42:50

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 7'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-16T06:01:51', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '00a9bae4-a4ce-4f06-a88a-de2bf839d447'	System	16 Sep 2020 13:02:01
User entered 'None (1)'	System	16 Sep 2020 13:02:01

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-16T06:01:53', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '00a9bae4-a4ce-4f06-a88a-de2bf839d447'	System	16 Sep 2020 13:02:01
User entered 'No (N)'	System	16 Sep 2020 13:02:01

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-16T06:01:54', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '00a9bae4-a4ce-4f06-a88a-de2bf839d447'	System	16 Sep 2020 13:02:01
User entered 'No (N)'	System	16 Sep 2020 13:02:01

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-16T06:01:56', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '00a9bae4-a4ce-4f06-a88a-de2bf839d447'	System	16 Sep 2020 13:02:01
User entered 'None (1)'	System	16 Sep 2020 13:02:01

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-16T06:01:57', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '00a9bae4-a4ce-4f06-a88a-de2bf839d447'	System	16 Sep 2020 13:02:01
User entered '16 Sep 2020 06:01'	System	16 Sep 2020 13:02:01

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T17:04:10', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'c73637a8-65bb-44be-b598-59453140749f' User entered 'None (0)'	System	10 Sep 2020 00:04:38
	System	10 Sep 2020 00:04:38

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T17:04:13', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'c73637a8-65bb-44be-b598-59453140749f' User entered 'None (0)'	System	10 Sep 2020 00:04:38
	System	10 Sep 2020 00:04:38

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T17:04:15', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'c73637a8-65bb-44be-b598-59453140749f' User entered 'None (0)'	System	10 Sep 2020 00:04:38
	System	10 Sep 2020 00:04:38

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T17:04:17', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'c73637a8-65bb-44be-b598-59453140749f' User entered 'None (0)'	System	10 Sep 2020 00:04:38
	System	10 Sep 2020 00:04:38

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T17:04:24', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'c73637a8-65bb-44be-b598-59453140749f' User entered 'None (0)'	System	10 Sep 2020 00:04:38
	System	10 Sep 2020 00:04:38

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T17:04:26', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'c73637a8-65bb-44be-b598-59453140749f' User entered 'None (0)'	System	10 Sep 2020 00:04:38
	System	10 Sep 2020 00:04:38

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

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)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T17:04:31', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'c73637a8-65bb-44be-b598-59453140749f'	System	10 Sep 2020 00:04:38
User entered 'No (N)'	System	10 Sep 2020 00:04:38

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T17:04:33', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'c73637a8-65bb-44be-b598-59453140749f' User entered '09 Sep 2020 17:04'	System	10 Sep 2020 00:04:38
	System	10 Sep 2020 00:04:38

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '09 Sep 2020 16:54'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '09 Sep 2020 19:24'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T21:39:19', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'd99f6872-b816-495f-9554-d56599b4db43' User entered 'None (0)'	System	10 Sep 2020 04:39:41
	System	10 Sep 2020 04:39:41

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T21:39:20', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'd99f6872-b816-495f-9554-d56599b4db43' User entered 'None (0)'	System	10 Sep 2020 04:39:41
	System	10 Sep 2020 04:39:41

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T21:39:22', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'd99f6872-b816-495f-9554-d56599b4db43' User entered 'None (0)'	System	10 Sep 2020 04:39:41
	System	10 Sep 2020 04:39:41

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T21:39:25', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'd99f6872-b816-495f-9554-d56599b4db43' User entered 'None (0)'	System	10 Sep 2020 04:39:41
	System	10 Sep 2020 04:39:41

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T21:39:27', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'd99f6872-b816-495f-9554-d56599b4db43' User entered 'None (0)'	System	10 Sep 2020 04:39:41
	System	10 Sep 2020 04:39:41

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T21:39:29', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'd99f6872-b816-495f-9554-d56599b4db43' User entered 'None (0)'	System	10 Sep 2020 04:39:41
	System	10 Sep 2020 04:39:41

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

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)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T21:39:34', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'd99f6872-b816-495f-9554-d56599b4db43'	System	10 Sep 2020 04:39:41
User entered 'No (N)'	System	10 Sep 2020 04:39:41

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-09T21:39:40', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'd99f6872-b816-495f-9554-d56599b4db43'	System	10 Sep 2020 04:39:41
User entered '09 Sep 2020 21:39'	System	10 Sep 2020 04:39:41

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '09 Sep 2020 20:19'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 2'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-10T21:15:06', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'bd5adb8f-fa23-4559-9f62-768bdbd66d5e'	System	11 Sep 2020 04:15:28
User entered 'None (0)'	System	11 Sep 2020 04:15:28

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-10T21:15:08', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'bd5adb8f-fa23-4559-9f62-768bdbd66d5e' User entered 'None (0)'	System	11 Sep 2020 04:15:28
	System	11 Sep 2020 04:15:28

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-10T21:15:10', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'bd5adb8f-fa23-4559-9f62-768bdbd66d5e' User entered 'None (0)'	System	11 Sep 2020 04:15:28
	System	11 Sep 2020 04:15:28

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-10T21:15:13', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'bd5adb8f-fa23-4559-9f62-768bdbd66d5e' User entered 'None (0)'	System	11 Sep 2020 04:15:28
	System	11 Sep 2020 04:15:28

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-10T21:15:15', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'bd5adb8f-fa23-4559-9f62-768bdbd66d5e' User entered 'None (0)'	System	11 Sep 2020 04:15:28
	System	11 Sep 2020 04:15:28

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-10T21:15:17', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'bd5adb8f-fa23-4559-9f62-768bdbd66d5e' User entered 'None (0)'	System	11 Sep 2020 04:15:28
	System	11 Sep 2020 04:15:28

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

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)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-10T21:15:19', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'bd5adb8f-fa23-4559-9f62-768bdbd66d5e'	System	11 Sep 2020 04:15:28
User entered 'No (N)'	System	11 Sep 2020 04:15:28

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-10T21:15:24', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'bd5adb8f-fa23-4559-9f62-768bdbd66d5e' User entered '10 Sep 2020 21:15'	System	11 Sep 2020 04:15:28
	System	11 Sep 2020 04:15:28

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 3'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-11T23:11:59', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '8195c636-c330-4a1d-b74f-4c09a8c99468' User entered 'None (0)'	System	12 Sep 2020 06:12:13
	System	12 Sep 2020 06:12:13

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-11T23:12:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '8195c636-c330-4a1d-b74f-4c09a8c99468' User entered 'None (0)'	System	12 Sep 2020 06:12:13
	System	12 Sep 2020 06:12:13

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-11T23:12:02', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '8195c636-c330-4a1d-b74f-4c09a8c99468' User entered 'None (0)'	System	12 Sep 2020 06:12:13
	System	12 Sep 2020 06:12:13

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-11T23:12:03', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '8195c636-c330-4a1d-b74f-4c09a8c99468' User entered 'None (0)'	System	12 Sep 2020 06:12:13
	System	12 Sep 2020 06:12:13

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-11T23:12:05', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '8195c636-c330-4a1d-b74f-4c09a8c99468' User entered 'None (0)'	System	12 Sep 2020 06:12:13
	System	12 Sep 2020 06:12:13

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-11T23:12:07', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '8195c636-c330-4a1d-b74f-4c09a8c99468' User entered 'None (0)'	System	12 Sep 2020 06:12:13
	System	12 Sep 2020 06:12:13

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

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)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-11T23:12:10', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '8195c636-c330-4a1d-b74f-4c09a8c99468'	System	12 Sep 2020 06:12:13
User entered 'No (N)'	System	12 Sep 2020 06:12:13

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-11T23:12:11', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '8195c636-c330-4a1d-b74f-4c09a8c99468'	System	12 Sep 2020 06:12:13
User entered '11 Sep 2020 23:12'	System	12 Sep 2020 06:12:13

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 4'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-12T21:32:18', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '191cbab1-468b-4e95-a7ab-d779f4525441' User entered 'None (0)'	System	13 Sep 2020 04:32:34
	System	13 Sep 2020 04:32:34

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-12T21:32:20', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '191cbab1-468b-4e95-a7ab-d779f4525441' User entered 'None (0)'	System	13 Sep 2020 04:32:34
	System	13 Sep 2020 04:32:34

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-12T21:32:22', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '191cbab1-468b-4e95-a7ab-d779f4525441' User entered 'None (0)'	System	13 Sep 2020 04:32:34
	System	13 Sep 2020 04:32:34

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-12T21:32:23', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '191cbab1-468b-4e95-a7ab-d779f4525441' User entered 'None (0)'	System	13 Sep 2020 04:32:34
	System	13 Sep 2020 04:32:34

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-12T21:32:25', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '191cbab1-468b-4e95-a7ab-d779f4525441' User entered 'None (0)'	System	13 Sep 2020 04:32:34
	System	13 Sep 2020 04:32:34

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-12T21:32:27', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '191cbab1-468b-4e95-a7ab-d779f4525441' User entered 'None (0)'	System	13 Sep 2020 04:32:34
	System	13 Sep 2020 04:32:34

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

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)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-12T21:32:29', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '191cbab1-468b-4e95-a7ab-d779f4525441'	System	13 Sep 2020 04:32:34
User entered 'No (N)'	System	13 Sep 2020 04:32:34

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-12T21:32:31', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '191cbab1-468b-4e95-a7ab-d779f4525441' User entered '12 Sep 2020 21:32'	System	13 Sep 2020 04:32:34
	System	13 Sep 2020 04:32:34

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 5'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-13T21:30:18', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'ade4e069-7b0b-4496-8b9c-02cbb30d52a9' User entered 'None (0)'	System	14 Sep 2020 04:30:34
	System	14 Sep 2020 04:30:34

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-13T21:30:20', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'ade4e069-7b0b-4496-8b9c-02cbb30d52a9' User entered 'None (0)'	System	14 Sep 2020 04:30:34
	System	14 Sep 2020 04:30:34

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-13T21:30:21', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'ade4e069-7b0b-4496-8b9c-02cbb30d52a9' User entered 'None (0)'	System	14 Sep 2020 04:30:34
	System	14 Sep 2020 04:30:34

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-13T21:30:22', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'ade4e069-7b0b-4496-8b9c-02cbb30d52a9' User entered 'None (0)'	System	14 Sep 2020 04:30:34
	System	14 Sep 2020 04:30:34

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-13T21:30:24', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'ade4e069-7b0b-4496-8b9c-02cbb30d52a9' User entered 'None (0)'	System	14 Sep 2020 04:30:34
	System	14 Sep 2020 04:30:34

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-13T21:30:25', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'ade4e069-7b0b-4496-8b9c-02cbb30d52a9' User entered 'None (0)'	System	14 Sep 2020 04:30:34
	System	14 Sep 2020 04:30:34

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

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)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-13T21:30:28', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'ade4e069-7b0b-4496-8b9c-02cbb30d52a9' User entered 'No (N)'	System	14 Sep 2020 04:30:34
	System	14 Sep 2020 04:30:34

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-13T21:30:30', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'ade4e069-7b0b-4496-8b9c-02cbb30d52a9' User entered '13 Sep 2020 21:30'	System	14 Sep 2020 04:30:34
	System	14 Sep 2020 04:30:34

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 6'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-15T07:42:24', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'e431a805-a37a-4b51-8296-3533d23735a0' User entered 'None (0)'	System	15 Sep 2020 14:42:39
	System	15 Sep 2020 14:42:39

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-15T07:42:26', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'e431a805-a37a-4b51-8296-3533d23735a0' User entered 'None (0)'	System	15 Sep 2020 14:42:39
	System	15 Sep 2020 14:42:39

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-15T07:42:27', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'e431a805-a37a-4b51-8296-3533d23735a0' User entered 'None (0)'	System	15 Sep 2020 14:42:39
	System	15 Sep 2020 14:42:39

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-15T07:42:30', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'e431a805-a37a-4b51-8296-3533d23735a0' User entered 'None (0)'	System	15 Sep 2020 14:42:39
	System	15 Sep 2020 14:42:39

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-15T07:42:31', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'e431a805-a37a-4b51-8296-3533d23735a0' User entered 'None (0)'	System	15 Sep 2020 14:42:39
	System	15 Sep 2020 14:42:39

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-15T07:42:33', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'e431a805-a37a-4b51-8296-3533d23735a0' User entered 'None (0)'	System	15 Sep 2020 14:42:39
	System	15 Sep 2020 14:42:39

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

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)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-15T07:42:35', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'e431a805-a37a-4b51-8296-3533d23735a0' User entered 'No (N)'	System	15 Sep 2020 14:42:39
	System	15 Sep 2020 14:42:39

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-15T07:42:36', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'e431a805-a37a-4b51-8296-3533d23735a0' User entered '15 Sep 2020 07:42'	System	15 Sep 2020 14:42:39
	System	15 Sep 2020 14:42:39

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 7'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-16T06:02:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '532de716-bba8-4009-b73a-e1b5bfddcfaa' User entered 'None (0)'	System	16 Sep 2020 13:02:13
	System	16 Sep 2020 13:02:13

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-16T06:02:02', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '532de716-bba8-4009-b73a-e1b5bfddcfaa' User entered 'None (0)'	System	16 Sep 2020 13:02:13
	System	16 Sep 2020 13:02:13

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-16T06:02:04', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '532de716-bba8-4009-b73a-e1b5bfddcfaf' User entered 'None (0)'	System	16 Sep 2020 13:02:13
	System	16 Sep 2020 13:02:13

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-16T06:02:05', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '532de716-bba8-4009-b73a-e1b5bfddcfaf' User entered 'None (0)'	System	16 Sep 2020 13:02:13
	System	16 Sep 2020 13:02:13

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-16T06:02:07', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '532de716-bba8-4009-b73a-e1b5bfddcfaa' User entered 'None (0)'	System	16 Sep 2020 13:02:13
	System	16 Sep 2020 13:02:13

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-16T06:02:08', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '532de716-bba8-4009-b73a-e1b5bfddcfaa'	System	16 Sep 2020 13:02:13
User entered 'None (0)'	System	16 Sep 2020 13:02:13

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

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)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-16T06:02:10', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '532de716-bba8-4009-b73a-e1b5bfddcfaa'	System	16 Sep 2020 13:02:13
User entered 'No (N)'	System	16 Sep 2020 13:02:13

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-09-16T06:02:12', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '532de716-bba8-4009-b73a-e1b5bfddcfaa' User entered '16 Sep 2020 06:02'	System	16 Sep 2020 13:02:13
	System	16 Sep 2020 13:02:13

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 23:55:23

US3462421

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:52:24
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	07 Oct 2020 23:44:13

US3462421

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:52:24
User entered '16 Sep 2020'	Danuel Hamlin (b) (4)	07 Oct 2020 23:44:13

US3462421

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:52:24
User entered 'Contact Made (CONTACT MADE)'	Danuel Hamlin (b) (4)	07 Oct 2020 23:44:13

US3462421

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:52:24
User entered empty.	Danuel Hamlin (b) (4)	07 Oct 2020 23:44:13

US3462421

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:52:28
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	07 Oct 2020 23:44:23

US3462421

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User entered 'I'	System	07 Oct 2020 23:44:23

US3462421

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:52:36
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	07 Oct 2020 23:44:45

US3462421

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:52:36
User entered '23 Sep 2020'	Danuel Hamlin (b) (4)	07 Oct 2020 23:44:45

US3462421

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:52:36
User entered 'Contact Made (CONTACT MADE)'	Danuel Hamlin (b) (4)	07 Oct 2020 23:44:45

US3462421

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:52:36
User entered empty.	Danuel Hamlin (b) (4)	07 Oct 2020 23:44:45

US3462421

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:52:42
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	07 Oct 2020 23:44:54

US3462421

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User entered 'I'	System	07 Oct 2020 23:44:54

US3462421

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:52:54
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	07 Oct 2020 23:45:09

US3462421

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:52:54
User entered '30 Sep 2020'	Danuel Hamlin (b) (4)	07 Oct 2020 23:45:09

US3462421

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:52:54
User entered 'Contact Made (CONTACT MADE)'	Danuel Hamlin (b) (4)	07 Oct 2020 23:45:09

US3462421

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:52:54
User entered empty.	Danuel Hamlin (b) (4)	07 Oct 2020 23:45:09

US3462421

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:52:58
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	07 Oct 2020 23:45:14

US3462421

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User entered 'I'	System	07 Oct 2020 23:45:14

US3462421

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:53:06
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	07 Oct 2020 23:45:31

US3462421

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:53:06
User entered '07 Oct 2020'	Danuel Hamlin (b) (4)	07 Oct 2020 23:45:31

US3462421

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:06
User entered 'Clinic (Clinic)'	Danuel Hamlin (b) (4)	07 Oct 2020 23:45:31

US3462421

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'VISIT2'	System	07 Oct 2020 23:45:31

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User accepted default value 'Pre-Dose (PREDOSE)'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered 'Yes (Y)'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered '07 Oct 2020'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered '15:27'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered '07 Oct 2020 15:27'	System	18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered '98.0' F		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered 'Other (Other)'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered 'TYMPANIC'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered '84'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'bpm'	System	18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered '12'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'breaths/min'	System	18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered '110'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'mmHg'	System	18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered '74'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'mmHg'	System	18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User accepted default value 'Post-Dose (POSTDOSE)'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered 'Yes (Y)'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered '07 Oct 2020'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered '16:42'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered '07 Oct 2020 16:42'	System	18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered '98.6' F		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered 'Other (Other)'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered 'TYMPANIC'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered '72'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'bpm'	System	18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered '16'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'breaths/min'	System	18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered '110'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'mmHg'	System	18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:26
User entered '64'		18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'mmHg'	System	18 Oct 2020 22:53:10

US3462421

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:35
User entered 'No (N)'		18 Oct 2020 22:53:16

US3462421

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:35
User entered empty.		18 Oct 2020 22:53:16

US3462421

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:47
User entered 'Yes (Y)'		02 Nov 2020 03:58:27

US3462421

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:47
User entered '07 Oct 2020'		02 Nov 2020 03:58:27

US3462421

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:47
User entered 'Urine (URINE)'		02 Nov 2020 03:58:27

US3462421

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:47
User entered 'Negative (NEGATIVE)'		02 Nov 2020 03:58:27

US3462421

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:47
User entered 'No (N)'		02 Nov 2020 03:58:27

US3462421

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:47
User entered empty.		02 Nov 2020 03:58:27

US3462421

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:53:47
User entered empty.		02 Nov 2020 03:58:27

US3462421

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered empty.	System	02 Nov 2020 03:58:27

US3462421

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:54:01
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	07 Oct 2020 23:45:59

US3462421

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:54:01
User entered empty.	Danuel Hamlin (b) (4)	07 Oct 2020 23:45:59

US3462421

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:54:01
User entered empty.	Danuel Hamlin (b) (4)	07 Oct 2020 23:45:59

US3462421

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 23:45:59

US3462421

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:54:01
User entered '07 Oct 2020'	Danuel Hamlin (b) (4)	07 Oct 2020 23:45:59

US3462421

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:54:01
User entered '16:10'	Danuel Hamlin (b) (4)	07 Oct 2020 23:45:59

US3462421

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered '07 Oct 2020 16:10'	System	07 Oct 2020 23:45:59

US3462421

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:54:01
User entered 'Left Arm (LEFT ARM)'	Danuel Hamlin (b) (4)	07 Oct 2020 23:45:59

US3462421

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
DataPoint Verified.		16 Dec 2020 20:54:01
User entered 'ONCE'	System	07 Oct 2020 23:45:59

US3462421

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 23:45:59

US3462421

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:54:24
User entered 'Yes (Y)'		18 Oct 2020 22:54:52

US3462421

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:54:24
User entered '07 Oct 2020'		18 Oct 2020 22:54:52

US3462421

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:54:24
User entered '16:01'		18 Oct 2020 22:54:52

US3462421

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered '07 Oct 2020 16:01'	System	18 Oct 2020 22:54:52

US3462421

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:41:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:54:31
User entered '07 Oct 2020'		18 Oct 2020 22:55:14

US3462421

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		18 Oct 2020 22:55:14

US3462421

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:54:31
User entered 'Yes (Y)'		18 Oct 2020 22:55:14

US3462421

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:54:31
User entered '16:03'		18 Oct 2020 22:55:14

US3462421

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered '07 Oct 2020 16:03'	System	18 Oct 2020 22:55:14

US3462421

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		18 Oct 2020 22:55:14

US3462421

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:54:31
User entered 'No (N)'		18 Oct 2020 22:55:14

US3462421

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:54:31
User entered empty.		18 Oct 2020 22:55:14

US3462421

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered empty.	System	18 Oct 2020 22:55:14

US3462421

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:54:36
User entered 'Yes (Y)'		18 Oct 2020 22:55:20

US3462421

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'I'	System	18 Oct 2020 22:55:20

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T16:46:23', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'a60311c1-83b9-4c41-a059-238ebc490e48' User entered 'Yes (Y)'	System	07 Oct 2020 23:46:37
	System	07 Oct 2020 23:46:37

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T16:46:27', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'a60311c1-83b9-4c41-a059-238ebc490e48' User entered '98.6'	System	07 Oct 2020 23:46:37
	System	07 Oct 2020 23:46:37

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T16:46:30', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'a60311c1-83b9-4c41-a059-238ebc490e48'	System	07 Oct 2020 23:46:37
User entered 'No (N)'	System	07 Oct 2020 23:46:37

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T16:46:33', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'a60311c1-83b9-4c41-a059-238ebc490e48' User entered '07 Oct 2020 16:46'	System	07 Oct 2020 23:46:37
	System	07 Oct 2020 23:46:37

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '07 Oct 2020 16:30'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '07 Oct 2020 19:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T21:24:15', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '418fde3c-79e9-436d-b851-f537b66eddec' User entered 'Yes (Y)'	System	08 Oct 2020 04:24:28
	System	08 Oct 2020 04:24:28

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T21:24:20', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '418fde3c-79e9-436d-b851-f537b66eddec' User entered '97.9'	System	08 Oct 2020 04:24:28
	System	08 Oct 2020 04:24:28

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T21:24:23', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '418fde3c-79e9-436d-b851-f537b66eddec'	System	08 Oct 2020 04:24:28
User entered 'No (N)'	System	08 Oct 2020 04:24:28

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T21:24:26', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '418fde3c-79e9-436d-b851-f537b66eddec'	System	08 Oct 2020 04:24:28
User entered '07 Oct 2020 21:24'	System	08 Oct 2020 04:24:28

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '07 Oct 2020 19:55'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 2'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-09T07:28:20', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '751c917c-9fd9-4ec5-92e1-7eb29c771056'	System	09 Oct 2020 14:28:31
User entered 'Yes (Y)'	System	09 Oct 2020 14:28:31

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-09T07:28:24', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '751c917c-9fd9-4ec5-92e1-7eb29c771056'	System	09 Oct 2020 14:28:31
User entered '98.0'	System	09 Oct 2020 14:28:31

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-09T07:28:26', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '751c917c-9fd9-4ec5-92e1-7eb29c771056'	System	09 Oct 2020 14:28:31
User entered 'No (N)'	System	09 Oct 2020 14:28:31

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-09T07:28:28', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '751c917c-9fd9-4ec5-92e1-7eb29c771056'	System	09 Oct 2020 14:28:31
User entered '09 Oct 2020 07:28'	System	09 Oct 2020 14:28:31

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 3'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-10T08:18:34', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'd20898ff-a19d-485a-b98c-c751f604f8dc' User entered 'Yes (Y)'	System	10 Oct 2020 15:18:41
	System	10 Oct 2020 15:18:41

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-10T08:18:37', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'd20898ff-a19d-485a-b98c-c751f604f8dc' User entered '97.1'	System	10 Oct 2020 15:18:41
	System	10 Oct 2020 15:18:41

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-10T08:18:39', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'd20898ff-a19d-485a-b98c-c751f604f8dc'	System	10 Oct 2020 15:18:41
User entered 'No (N)'	System	10 Oct 2020 15:18:41

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-10T08:18:40', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'd20898ff-a19d-485a-b98c-c751f604f8dc' User entered '10 Oct 2020 08:18'	System	10 Oct 2020 15:18:41
	System	10 Oct 2020 15:18:41

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 4'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T09:53:14', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'eda31703-3eff-458f-9787-bf4031ef1995'	System	11 Oct 2020 16:53:21
User entered 'No (N)'	System	11 Oct 2020 16:53:21

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T09:53:16', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'eda31703-3eff-458f-9787-bf4031ef1995'	System	11 Oct 2020 16:53:21
User entered 'No (N)'	System	11 Oct 2020 16:53:21

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T09:53:18', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'eda31703-3eff-458f-9787-bf4031ef1995'	System	11 Oct 2020 16:53:21
User entered '11 Oct 2020 09:53'	System	11 Oct 2020 16:53:21

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 5'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T21:33:39', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '84620fd6-334a-4f75-9d34-1cc7c26fd4e5'	System	12 Oct 2020 04:33:49
User entered 'Yes (Y)'	System	12 Oct 2020 04:33:49

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T21:33:42', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '84620fd6-334a-4f75-9d34-1cc7c26fd4e5' User entered '97.6'	System	12 Oct 2020 04:33:49
	System	12 Oct 2020 04:33:49

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T21:33:44', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '84620fd6-334a-4f75-9d34-1cc7c26fd4e5'	System	12 Oct 2020 04:33:49
User entered 'No (N)'	System	12 Oct 2020 04:33:49

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T21:33:46', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '84620fd6-334a-4f75-9d34-1cc7c26fd4e5'	System	12 Oct 2020 04:33:49
User entered '11 Oct 2020 21:33'	System	12 Oct 2020 04:33:49

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 6'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-13T05:37:53', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1854b2bf-398e-4ee1-887b-b727d1ec81ef' User entered 'Yes (Y)'	System	13 Oct 2020 12:38:13
	System	13 Oct 2020 12:38:13

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-13T05:38:05', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1854b2bf-398e-4ee1-887b-b727d1ec81ef' User entered '97.7'	System	13 Oct 2020 12:38:13
	System	13 Oct 2020 12:38:13

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-13T05:38:08', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1854b2bf-398e-4ee1-887b-b727d1ec81ef'	System	13 Oct 2020 12:38:13
User entered 'No (N)'	System	13 Oct 2020 12:38:13

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-13T05:38:10', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1854b2bf-398e-4ee1-887b-b727d1ec81ef' User entered '13 Oct 2020 05:38'	System	13 Oct 2020 12:38:13
	System	13 Oct 2020 12:38:13

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 7'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-14T08:44:23', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '2323c1af-1efe-4e00-bf25-099438b914d1' User entered 'Yes (Y)'	System	14 Oct 2020 15:45:39
	System	14 Oct 2020 15:45:39

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-14T08:45:22', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '2323c1af-1efe-4e00-bf25-099438b914d1' User entered '98.2'	System	14 Oct 2020 15:45:39
	System	14 Oct 2020 15:45:39

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-14T08:45:24', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '2323c1af-1efe-4e00-bf25-099438b914d1'	System	14 Oct 2020 15:45:39
User entered 'No (N)'	System	14 Oct 2020 15:45:39

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-14T08:45:26', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '2323c1af-1efe-4e00-bf25-099438b914d1'	System	14 Oct 2020 15:45:39
User entered '14 Oct 2020 08:45'	System	14 Oct 2020 15:45:39

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T16:46:38', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '963cfe93-edc2-43ba-bbe0-ed480bde1beb' User entered 'None (1)'	System	07 Oct 2020 23:46:51
	System	07 Oct 2020 23:46:51

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T16:46:42', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '963cfe93-edc2-43ba-bbe0-ed480bde1beb' User entered 'No (N)'	System	07 Oct 2020 23:46:51
	System	07 Oct 2020 23:46:51

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T16:46:45', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '963cfe93-edc2-43ba-bbe0-ed480bde1beb' User entered 'No (N)'	System	07 Oct 2020 23:46:51
	System	07 Oct 2020 23:46:51

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T16:46:47', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '963cfe93-edc2-43ba-bbe0-ed480bde1beb' User entered 'None (1)'	System	07 Oct 2020 23:46:51
	System	07 Oct 2020 23:46:51

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T16:46:49', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '963cfe93-edc2-43ba-bbe0-ed480bde1beb' User entered '07 Oct 2020 16:46'	System	07 Oct 2020 23:46:51
	System	07 Oct 2020 23:46:51

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '07 Oct 2020 16:30'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '07 Oct 2020 19:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T21:24:29', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '3ff52c04-c905-4366-8651-0962f9453844' User entered 'None (1)'	System	08 Oct 2020 04:24:42
	System	08 Oct 2020 04:24:42

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T21:24:31', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '3ff52c04-c905-4366-8651-0962f9453844'	System	08 Oct 2020 04:24:42
User entered 'No (N)'	System	08 Oct 2020 04:24:42

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T21:24:33', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '3ff52c04-c905-4366-8651-0962f9453844'	System	08 Oct 2020 04:24:42
User entered 'No (N)'	System	08 Oct 2020 04:24:42

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T21:24:36', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '3ff52c04-c905-4366-8651-0962f9453844'	System	08 Oct 2020 04:24:42
User entered 'None (1)'	System	08 Oct 2020 04:24:42

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T21:24:38', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '3ff52c04-c905-4366-8651-0962f9453844'	System	08 Oct 2020 04:24:42
User entered '07 Oct 2020 21:24'	System	08 Oct 2020 04:24:42

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '07 Oct 2020 19:55'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 2'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-09T07:28:31', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'c2847314-d489-47f1-b076-20415bc7500e' User entered 'None (1)'	System	09 Oct 2020 14:28:41
	System	09 Oct 2020 14:28:41

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-09T07:28:33', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'c2847314-d489-47f1-b076-20415bc7500e' User entered 'No (N)'	System	09 Oct 2020 14:28:41
	System	09 Oct 2020 14:28:41

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-09T07:28:35', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'c2847314-d489-47f1-b076-20415bc7500e' User entered 'No (N)'	System	09 Oct 2020 14:28:41
	System	09 Oct 2020 14:28:41

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-09T07:28:36', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'c2847314-d489-47f1-b076-20415bc7500e' User entered 'None (1)'	System	09 Oct 2020 14:28:41
	System	09 Oct 2020 14:28:41

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-09T07:28:38', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'c2847314-d489-47f1-b076-20415bc7500e' User entered '09 Oct 2020 07:28'	System	09 Oct 2020 14:28:41
	System	09 Oct 2020 14:28:41

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 3'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-10T08:18:43', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'd2cd112b-f62f-4404-88cf-3fc8ab32e043' User entered 'None (1)'	System	10 Oct 2020 15:18:51
	System	10 Oct 2020 15:18:51

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-10T08:18:45', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'd2cd112b-f62f-4404-88cf-3fc8ab32e043' User entered 'No (N)'	System	10 Oct 2020 15:18:51
	System	10 Oct 2020 15:18:51

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-10T08:18:47', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'd2cd112b-f62f-4404-88cf-3fc8ab32e043'	System	10 Oct 2020 15:18:51
User entered 'No (N)'	System	10 Oct 2020 15:18:51

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-10T08:18:48', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'd2cd112b-f62f-4404-88cf-3fc8ab32e043' User entered 'None (1)'	System	10 Oct 2020 15:18:51
	System	10 Oct 2020 15:18:51

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-10T08:18:50', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'd2cd112b-f62f-4404-88cf-3fc8ab32e043'	System	10 Oct 2020 15:18:51
User entered '10 Oct 2020 08:18'	System	10 Oct 2020 15:18:51

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 4'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T09:53:21', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '8682314a-ee91-4d6c-89ee-8296f9334192' User entered 'None (1)'	System	11 Oct 2020 16:53:29
	System	11 Oct 2020 16:53:29

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T09:53:22', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '8682314a-ee91-4d6c-89ee-8296f9334192'	System	11 Oct 2020 16:53:29
User entered 'No (N)'	System	11 Oct 2020 16:53:29

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T09:53:23', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '8682314a-ee91-4d6c-89ee-8296f9334192'	System	11 Oct 2020 16:53:29
User entered 'No (N)'	System	11 Oct 2020 16:53:29

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T09:53:25', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '8682314a-ee91-4d6c-89ee-8296f9334192'	System	11 Oct 2020 16:53:29
User entered 'None (1)'	System	11 Oct 2020 16:53:29

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T09:53:27', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '8682314a-ee91-4d6c-89ee-8296f9334192'	System	11 Oct 2020 16:53:29
User entered '11 Oct 2020 09:53'	System	11 Oct 2020 16:53:29

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 5'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T21:33:49', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '92645046-d19a-44d0-8d13-534b97d35047' User entered 'None (1)'	System	12 Oct 2020 04:33:57
	System	12 Oct 2020 04:33:57

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T21:33:50', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '92645046-d19a-44d0-8d13-534b97d35047'	System	12 Oct 2020 04:33:57
User entered 'No (N)'	System	12 Oct 2020 04:33:57

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T21:33:51', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '92645046-d19a-44d0-8d13-534b97d35047'	System	12 Oct 2020 04:33:57
User entered 'No (N)'	System	12 Oct 2020 04:33:57

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T21:33:53', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '92645046-d19a-44d0-8d13-534b97d35047' User entered 'None (1)'	System	12 Oct 2020 04:33:57
	System	12 Oct 2020 04:33:57

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T21:33:55', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '92645046-d19a-44d0-8d13-534b97d35047'	System	12 Oct 2020 04:33:57
User entered '11 Oct 2020 21:33'	System	12 Oct 2020 04:33:57

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 6'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-13T05:37:38', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '60e04bf4-9ddf-4a0b-85e4-0a0e024ad4e1' User entered 'None (1)'	System	13 Oct 2020 12:37:50
	System	13 Oct 2020 12:37:50

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-13T05:37:40', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '60e04bf4-9ddf-4a0b-85e4-0a0e024ad4e1' User entered 'No (N)'	System	13 Oct 2020 12:37:50
	System	13 Oct 2020 12:37:50

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-13T05:37:42', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '60e04bf4-9ddf-4a0b-85e4-0a0e024ad4e1' User entered 'No (N)'	System	13 Oct 2020 12:37:50
	System	13 Oct 2020 12:37:50

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-13T05:37:43', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '60e04bf4-9ddf-4a0b-85e4-0a0e024ad4e1' User entered 'None (1)'	System	13 Oct 2020 12:37:50
	System	13 Oct 2020 12:37:50

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-13T05:37:46', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '60e04bf4-9ddf-4a0b-85e4-0a0e024ad4e1' User entered '13 Oct 2020 05:37'	System	13 Oct 2020 12:37:50
	System	13 Oct 2020 12:37:50

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 7'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-14T08:44:02', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '56217198-2ef4-4de6-b253-034e053d02d3' User entered 'None (1)'	System	14 Oct 2020 15:44:31
	System	14 Oct 2020 15:44:31

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-14T08:44:03', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '56217198-2ef4-4de6-b253-034e053d02d3' User entered 'No (N)'	System	14 Oct 2020 15:44:31
	System	14 Oct 2020 15:44:31

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-14T08:44:04', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '56217198-2ef4-4de6-b253-034e053d02d3' User entered 'No (N)'	System	14 Oct 2020 15:44:31
	System	14 Oct 2020 15:44:31

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-14T08:44:06', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '56217198-2ef4-4de6-b253-034e053d02d3' User entered 'None (1)'	System	14 Oct 2020 15:44:31
	System	14 Oct 2020 15:44:31

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-14T08:44:08', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '56217198-2ef4-4de6-b253-034e053d02d3' User entered '14 Oct 2020 08:44'	System	14 Oct 2020 15:44:31
	System	14 Oct 2020 15:44:31

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T16:46:52', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'cfb7db78-e18b-4c08-b33b-b25672e0816e' User entered 'None (0)'	System	07 Oct 2020 23:47:13
	System	07 Oct 2020 23:47:13

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T16:46:54', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'cfb7db78-e18b-4c08-b33b-b25672e0816e' User entered 'None (0)'	System	07 Oct 2020 23:47:13
	System	07 Oct 2020 23:47:13

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T16:46:55', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'cfb7db78-e18b-4c08-b33b-b25672e0816e' User entered 'None (0)'	System	07 Oct 2020 23:47:13
	System	07 Oct 2020 23:47:13

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T16:46:56', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'cfb7db78-e18b-4c08-b33b-b25672e0816e' User entered 'None (0)'	System	07 Oct 2020 23:47:13
	System	07 Oct 2020 23:47:13

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T16:46:58', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'cfb7db78-e18b-4c08-b33b-b25672e0816e' User entered 'None (0)'	System	07 Oct 2020 23:47:13
	System	07 Oct 2020 23:47:13

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T16:46:59', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'cfb7db78-e18b-4c08-b33b-b25672e0816e' User entered 'None (0)'	System	07 Oct 2020 23:47:13
	System	07 Oct 2020 23:47:13

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

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)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T16:47:08', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'cfb7db78-e18b-4c08-b33b-b25672e0816e' User entered 'No (N)'	System	07 Oct 2020 23:47:13
	System	07 Oct 2020 23:47:13

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T16:47:10', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'cfb7db78-e18b-4c08-b33b-b25672e0816e' User entered '07 Oct 2020 16:47'	System	07 Oct 2020 23:47:13
	System	07 Oct 2020 23:47:13

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '07 Oct 2020 16:30'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '07 Oct 2020 19:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T21:24:41', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '93e81ffa-4d84-43a4-b51d-42da0afa9254'	System	08 Oct 2020 04:24:57
User entered 'None (0)'	System	08 Oct 2020 04:24:57

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T21:24:42', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '93e81ffa-4d84-43a4-b51d-42da0afa9254'	System	08 Oct 2020 04:24:57
User entered 'None (0)'	System	08 Oct 2020 04:24:57

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T21:24:43', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '93e81ffa-4d84-43a4-b51d-42da0afa9254'	System	08 Oct 2020 04:24:57
User entered 'None (0)'	System	08 Oct 2020 04:24:57

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T21:24:45', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '93e81ffa-4d84-43a4-b51d-42da0afa9254' User entered 'None (0)'	System	08 Oct 2020 04:24:57
	System	08 Oct 2020 04:24:57

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T21:24:47', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '93e81ffa-4d84-43a4-b51d-42da0afa9254' User entered 'None (0)'	System	08 Oct 2020 04:24:57
	System	08 Oct 2020 04:24:57

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T21:24:48', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '93e81ffa-4d84-43a4-b51d-42da0afa9254'	System	08 Oct 2020 04:24:57
User entered 'None (0)'	System	08 Oct 2020 04:24:57

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

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)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T21:24:50', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '93e81ffa-4d84-43a4-b51d-42da0afa9254'	System	08 Oct 2020 04:24:57
User entered 'No (N)'	System	08 Oct 2020 04:24:57

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-07T21:24:54', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '93e81ffa-4d84-43a4-b51d-42da0afa9254'	System	08 Oct 2020 04:24:57
User entered '07 Oct 2020 21:24'	System	08 Oct 2020 04:24:57

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '07 Oct 2020 19:55'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 2'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-09T07:28:41', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1a7403ec-5663-4655-bfdf-827b52454b38' User entered 'None (0)'	System	09 Oct 2020 14:29:03
	System	09 Oct 2020 14:29:03

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-09T07:28:43', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1a7403ec-5663-4655-bfdf-827b52454b38' User entered 'None (0)'	System	09 Oct 2020 14:29:03
	System	09 Oct 2020 14:29:03

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-09T07:28:44', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1a7403ec-5663-4655-bfdf-827b52454b38' User entered 'None (0)'	System	09 Oct 2020 14:29:03
	System	09 Oct 2020 14:29:03

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-09T07:28:47', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1a7403ec-5663-4655-bfdf-827b52454b38' User entered 'None (0)'	System	09 Oct 2020 14:29:03
	System	09 Oct 2020 14:29:03

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-09T07:28:48', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1a7403ec-5663-4655-bfdf-827b52454b38'	System	09 Oct 2020 14:29:03
User entered 'None (0)'	System	09 Oct 2020 14:29:03

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-09T07:28:51', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1a7403ec-5663-4655-bfdf-827b52454b38' User entered 'None (0)'	System	09 Oct 2020 14:29:03
	System	09 Oct 2020 14:29:03

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

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)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-09T07:28:53', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1a7403ec-5663-4655-bfdf-827b52454b38'	System	09 Oct 2020 14:29:03
User entered 'No (N)'	System	09 Oct 2020 14:29:03

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-09T07:28:56', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1a7403ec-5663-4655-bfdf-827b52454b38'	System	09 Oct 2020 14:29:03
User entered '09 Oct 2020 07:28'	System	09 Oct 2020 14:29:03

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 3'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-10T08:18:52', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '750a41d5-bc08-42be-b3aa-7042e1aa1503' User entered 'None (0)'	System	10 Oct 2020 15:19:07
	System	10 Oct 2020 15:19:07

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-10T08:18:53', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '750a41d5-bc08-42be-b3aa-7042e1aa1503' User entered 'None (0)'	System	10 Oct 2020 15:19:07
	System	10 Oct 2020 15:19:07

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-10T08:18:55', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '750a41d5-bc08-42be-b3aa-7042e1aa1503'	System	10 Oct 2020 15:19:07
User entered 'None (0)'	System	10 Oct 2020 15:19:07

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-10T08:18:56', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '750a41d5-bc08-42be-b3aa-7042e1aa1503' User entered 'None (0)'	System	10 Oct 2020 15:19:07
	System	10 Oct 2020 15:19:07

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-10T08:18:57', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '750a41d5-bc08-42be-b3aa-7042e1aa1503' User entered 'None (0)'	System	10 Oct 2020 15:19:07
	System	10 Oct 2020 15:19:07

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-10T08:18:59', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '750a41d5-bc08-42be-b3aa-7042e1aa1503' User entered 'None (0)'	System	10 Oct 2020 15:19:07
	System	10 Oct 2020 15:19:07

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

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)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-10T08:19:03', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '750a41d5-bc08-42be-b3aa-7042e1aa1503'	System	10 Oct 2020 15:19:07
User entered 'No (N)'	System	10 Oct 2020 15:19:07

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-10T08:19:05', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '750a41d5-bc08-42be-b3aa-7042e1aa1503'	System	10 Oct 2020 15:19:07
User entered '10 Oct 2020 08:19'	System	10 Oct 2020 15:19:07

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 4'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T09:53:29', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'f9adf596-64e7-4043-aef8-dd91c4851638' User entered 'None (0)'	System	11 Oct 2020 16:53:41
	System	11 Oct 2020 16:53:41

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T09:53:30', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'f9adf596-64e7-4043-aef8-dd91c4851638' User entered 'None (0)'	System	11 Oct 2020 16:53:41
	System	11 Oct 2020 16:53:41

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T09:53:32', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'f9adf596-64e7-4043-aef8-dd91c4851638' User entered 'None (0)'	System	11 Oct 2020 16:53:41
	System	11 Oct 2020 16:53:41

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T09:53:33', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'f9adf596-64e7-4043-aef8-dd91c4851638' User entered 'None (0)'	System	11 Oct 2020 16:53:41
	System	11 Oct 2020 16:53:41

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T09:53:34', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'f9adf596-64e7-4043-aef8-dd91c4851638' User entered 'None (0)'	System	11 Oct 2020 16:53:41
	System	11 Oct 2020 16:53:41

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T09:53:35', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'f9adf596-64e7-4043-aef8-dd91c4851638' User entered 'None (0)'	System	11 Oct 2020 16:53:41
	System	11 Oct 2020 16:53:41

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

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)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T09:53:36', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'f9adf596-64e7-4043-aef8-dd91c4851638'	System	11 Oct 2020 16:53:41
User entered 'No (N)'	System	11 Oct 2020 16:53:41

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T09:53:38', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'f9adf596-64e7-4043-aef8-dd91c4851638'	System	11 Oct 2020 16:53:41
User entered '11 Oct 2020 09:53'	System	11 Oct 2020 16:53:41

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 5'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T21:33:57', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'a5f8875c-d126-4e76-a244-0dd2e601076f' User entered 'None (0)'	System	12 Oct 2020 04:34:09
	System	12 Oct 2020 04:34:09

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T21:33:58', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'a5f8875c-d126-4e76-a244-0dd2e601076f' User entered 'None (0)'	System	12 Oct 2020 04:34:09
	System	12 Oct 2020 04:34:09

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T21:34:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'a5f8875c-d126-4e76-a244-0dd2e601076f' User entered 'None (0)'	System	12 Oct 2020 04:34:09
	System	12 Oct 2020 04:34:09

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T21:34:01', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'a5f8875c-d126-4e76-a244-0dd2e601076f' User entered 'None (0)'	System	12 Oct 2020 04:34:09
	System	12 Oct 2020 04:34:09

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T21:34:02', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'a5f8875c-d126-4e76-a244-0dd2e601076f' User entered 'None (0)'	System	12 Oct 2020 04:34:09
	System	12 Oct 2020 04:34:09

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T21:34:04', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'a5f8875c-d126-4e76-a244-0dd2e601076f' User entered 'None (0)'	System	12 Oct 2020 04:34:09
	System	12 Oct 2020 04:34:09

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

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)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T21:34:05', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'a5f8875c-d126-4e76-a244-0dd2e601076f' User entered 'No (N)'	System	12 Oct 2020 04:34:09
	System	12 Oct 2020 04:34:09

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-11T21:34:07', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'a5f8875c-d126-4e76-a244-0dd2e601076f' User entered '11 Oct 2020 21:34'	System	12 Oct 2020 04:34:09
	System	12 Oct 2020 04:34:09

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 6'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-13T05:37:21', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '9eb47a57-6c5e-4b23-97e7-6c99721d3148' User entered 'None (0)'	System	13 Oct 2020 12:37:39
	System	13 Oct 2020 12:37:39

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-13T05:37:23', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '9eb47a57-6c5e-4b23-97e7-6c99721d3148' User entered 'None (0)'	System	13 Oct 2020 12:37:39
	System	13 Oct 2020 12:37:39

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-13T05:37:24', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '9eb47a57-6c5e-4b23-97e7-6c99721d3148' User entered 'None (0)'	System	13 Oct 2020 12:37:39
	System	13 Oct 2020 12:37:39

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-13T05:37:25', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '9eb47a57-6c5e-4b23-97e7-6c99721d3148' User entered 'None (0)'	System	13 Oct 2020 12:37:39
	System	13 Oct 2020 12:37:39

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-13T05:37:27', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '9eb47a57-6c5e-4b23-97e7-6c99721d3148' User entered 'None (0)'	System	13 Oct 2020 12:37:39
	System	13 Oct 2020 12:37:39

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-13T05:37:28', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '9eb47a57-6c5e-4b23-97e7-6c99721d3148' User entered 'None (0)'	System	13 Oct 2020 12:37:39
	System	13 Oct 2020 12:37:39

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

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)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-13T05:37:30', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '9eb47a57-6c5e-4b23-97e7-6c99721d3148' User entered 'No (N)'	System	13 Oct 2020 12:37:39
	System	13 Oct 2020 12:37:39

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-13T05:37:32', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '9eb47a57-6c5e-4b23-97e7-6c99721d3148' User entered '13 Oct 2020 05:37'	System	13 Oct 2020 12:37:39
	System	13 Oct 2020 12:37:39

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	07 Oct 2020 23:45:59
User entered 'Day 7'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-14T08:44:10', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'acd7acc6-497c-4d6e-91fa-69ab319f4dc0' User entered 'None (0)'	System	14 Oct 2020 15:44:40
	System	14 Oct 2020 15:44:40

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-14T08:44:11', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'acd7acc6-497c-4d6e-91fa-69ab319f4dc0' User entered 'None (0)'	System	14 Oct 2020 15:44:40
	System	14 Oct 2020 15:44:40

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-14T08:44:12', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'acd7acc6-497c-4d6e-91fa-69ab319f4dc0' User entered 'None (0)'	System	14 Oct 2020 15:44:40
	System	14 Oct 2020 15:44:40

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-14T08:44:14', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'acd7acc6-497c-4d6e-91fa-69ab319f4dc0' User entered 'None (0)'	System	14 Oct 2020 15:44:40
	System	14 Oct 2020 15:44:40

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-14T08:44:15', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'acd7acc6-497c-4d6e-91fa-69ab319f4dc0' User entered 'None (0)'	System	14 Oct 2020 15:44:40
	System	14 Oct 2020 15:44:40

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-14T08:44:16', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'acd7acc6-497c-4d6e-91fa-69ab319f4dc0' User entered 'None (0)'	System	14 Oct 2020 15:44:40
	System	14 Oct 2020 15:44:40

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

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)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-14T08:44:18', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'acd7acc6-497c-4d6e-91fa-69ab319f4dc0'	System	14 Oct 2020 15:44:40
User entered 'No (N)'	System	14 Oct 2020 15:44:40

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-10-14T08:44:19', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'acd7acc6-497c-4d6e-91fa-69ab319f4dc0' User entered '14 Oct 2020 08:44'	System	14 Oct 2020 15:44:40
	System	14 Oct 2020 15:44:40

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 23:45:59

US3462421

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:41:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 23:45:59

US3462421

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:54:50
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	09 Nov 2020 06:03:53

US3462421

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:54:50
User entered '14 Oct 2020'	Danuel Hamlin (b) (4)	09 Nov 2020 06:03:53

US3462421

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:54:50
User entered 'Contact Made (CONTACT MADE)'	Danuel Hamlin (b) (4)	09 Nov 2020 06:03:53

US3462421

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:54:50
User entered empty.	Danuel Hamlin (b) (4)	09 Nov 2020 06:03:53

US3462421

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:54:57
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	09 Nov 2020 06:04:00

US3462421

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User entered 'I'	System	09 Nov 2020 06:04:00

US3462421

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:55:03
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	09 Nov 2020 06:04:16

US3462421

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:55:03
User entered '21 Oct 2020'	Danuel Hamlin (b) (4)	09 Nov 2020 06:04:16

US3462421

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:55:03
User entered 'Contact Made (CONTACT MADE)'	Danuel Hamlin (b) (4)	09 Nov 2020 06:04:16

US3462421

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:55:03
User entered empty.	Danuel Hamlin (b) (4)	09 Nov 2020 06:04:16

US3462421

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:55:10
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	09 Nov 2020 06:04:21

US3462421

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User entered 'I'	System	09 Nov 2020 06:04:21

US3462421

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:55:20
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	09 Nov 2020 06:04:39

US3462421

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:55:20
User entered '28 Oct 2020'	Danuel Hamlin (b) (4)	09 Nov 2020 06:04:39

US3462421

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:55:20
User entered 'Contact Made (CONTACT MADE)'	Danuel Hamlin (b) (4)	09 Nov 2020 06:04:39

US3462421

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:55:20
User entered empty.	Danuel Hamlin (b) (4)	09 Nov 2020 06:04:39

US3462421

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:55:26
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	09 Nov 2020 06:04:46

US3462421

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:20
User entered 'I'	System	09 Nov 2020 06:04:46

US3462421

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:55:33
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:02

US3462421

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:55:33
User entered '04 Nov 2020'	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:02

US3462421

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:55:33
User entered 'Clinic (Clinic)'	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:02

US3462421

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'VISIT3'	System	09 Nov 2020 06:05:02

US3462421

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:55:38
User entered 'No (N)'	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:14

US3462421

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:55:38
User entered empty.	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:14

US3462421

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:55:38
User entered empty.	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:14

US3462421

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered empty.	System	09 Nov 2020 06:05:14

US3462421

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:55:38
User entered empty.	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:14

US3462421

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:55:38
User entered empty.	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:14

US3462421

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:55:38
User entered empty.	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:14

US3462421

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:55:38
User entered empty.	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:14

US3462421

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered empty.	System	09 Nov 2020 06:05:14

US3462421

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:55:38
User entered empty.	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:14

US3462421

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered empty.	System	09 Nov 2020 06:05:14

US3462421

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:55:38
User entered empty.	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:14

US3462421

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered empty.	System	09 Nov 2020 06:05:14

US3462421

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:55:38
User entered empty.	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:14

US3462421

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered empty.	System	09 Nov 2020 06:05:14

US3462421

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22

US3462421

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22

US3462421

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:55:44
User entered 'No (N)'	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:21

US3462421

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:55:44
User entered empty.	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:21

US3462421

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:55:53
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:40

US3462421

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:55:53
User entered '04 Nov 2020'	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:40

US3462421

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 20:55:53
User entered '15:35'	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:40

US3462421

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered '04 Nov 2020 15:35'	System	09 Nov 2020 06:05:40

US3462421

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:06:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:56:01
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	09 Nov 2020 06:05:46

US3462421

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'I'	System	09 Nov 2020 06:05:46

US3462421

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 64'	System	09 Sep 2020 23:55:23

US3462421

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

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 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-11-11T12:00:35', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '60c12c19-8d6e-4b77-8b9f-85d6244a9c97'	System	11 Nov 2020 20:00:43
User entered 'No (N)'	System	11 Nov 2020 20:00:43

US3462421

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-11-11T12:00:38', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '60c12c19-8d6e-4b77-8b9f-85d6244a9c97'	System	11 Nov 2020 20:00:43
User entered 'No (N)'	System	11 Nov 2020 20:00:43

US3462421

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-11-11T12:00:40', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '60c12c19-8d6e-4b77-8b9f-85d6244a9c97'	System	11 Nov 2020 20:00:43
User entered '11 Nov 2020 12:00:40'	System	11 Nov 2020 20:00:43

US3462421

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered '09 Nov 2020 00:01'	System	09 Sep 2020 23:55:23

US3462421

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered '13 Nov 2020 23:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered 'Day 71'	System	09 Sep 2020 23:55:23

US3462421

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-11-16T07:35:38', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '5e256fa3-46d8-4e9d-82c1-ebbd2bce3ff8'	System	16 Nov 2020 15:35:47
User entered 'No (N)'	System	16 Nov 2020 15:35:47

US3462421

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-11-16T07:35:41', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '5e256fa3-46d8-4e9d-82c1-ebbd2bce3ff8'	System	16 Nov 2020 15:35:47
User entered 'No (N)'	System	16 Nov 2020 15:35:47

US3462421

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-11-16T07:35:44', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '5e256fa3-46d8-4e9d-82c1-ebbd2bce3ff8' User entered '16 Nov 2020 07:35:44'	System	16 Nov 2020 15:35:47
	System	16 Nov 2020 15:35:47

US3462421

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered '16 Nov 2020 00:01'	System	09 Sep 2020 23:55:23

US3462421

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:03:57
Data entry locked.	System	09 Sep 2020 23:55:23
User entered '20 Nov 2020 23:59'	System	09 Sep 2020 23:55:23

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-11-23T05:34:29', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '75b41f61-b987-4d69-93dc-18c8cae666ad' User entered 'No (N)'	System	23 Nov 2020 13:34:41
	System	23 Nov 2020 13:34:41

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-11-23T05:34:36', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '75b41f61-b987-4d69-93dc-18c8cae666ad' User entered 'No (N)'	System	23 Nov 2020 13:34:41

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-11-23T05:34:38', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '75b41f61-b987-4d69-93dc-18c8cae666ad' User entered '23 Nov 2020 05:34:38'	System	23 Nov 2020 13:34:41
	System	23 Nov 2020 13:34:41

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-11-27T08:01:46', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'bf213386-51f1-46d7-8470-f7c866523ffe' User entered 'No (N)'	System	27 Nov 2020 16:01:59
	System	27 Nov 2020 16:01:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-11-27T08:01:54', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'bf213386-51f1-46d7-8470-f7c866523ffe' User entered 'No (N)'	System	27 Nov 2020 16:01:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-11-27T08:01:57', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'bf213386-51f1-46d7-8470-f7c866523ffe' User entered '27 Nov 2020 08:01:57'	System	27 Nov 2020 16:01:59
	System	27 Nov 2020 16:01:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-12-04T06:22:36', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '9c6b9420-8842-4eb8-ba42-f1e6fc63ff6b' User entered 'No (N)'	System	04 Dec 2020 14:22:43
	System	04 Dec 2020 14:22:43

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-12-04T06:22:39', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '9c6b9420-8842-4eb8-ba42-f1e6fc63ff6b' User entered 'No (N)'	System	04 Dec 2020 14:22:43

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-12-04T06:22:41', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '9c6b9420-8842-4eb8-ba42-f1e6fc63ff6b' User entered '04 Dec 2020 06:22:41'	System	04 Dec 2020 14:22:43
	System	04 Dec 2020 14:22:43

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-12-11T06:43:56', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '56a0f6fc-4633-4648-af02-97b005961981' User entered 'No (N)'	System	11 Dec 2020 14:44:04
	System	11 Dec 2020 14:44:04

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-12-11T06:43:58', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '56a0f6fc-4633-4648-af02-97b005961981' User entered 'No (N)'	System	11 Dec 2020 14:44:04
	System	11 Dec 2020 14:44:04

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-12-11T06:44:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '56a0f6fc-4633-4648-af02-97b005961981' User entered '11 Dec 2020 06:44:00'	System	11 Dec 2020 14:44:04
	System	11 Dec 2020 14:44:04

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-12-18T23:05:41', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '6ce9d134-1ab4-4231-b687-e266b363b4da' User entered 'No (N)'	System	19 Dec 2020 07:05:48
	System	19 Dec 2020 07:05:48

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-12-18T23:05:43', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '6ce9d134-1ab4-4231-b687-e266b363b4da' User entered 'No (N)'	System	19 Dec 2020 07:05:48
	System	19 Dec 2020 07:05:48

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-12-18T23:05:45', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '6ce9d134-1ab4-4231-b687-e266b363b4da' User entered '18 Dec 2020 23:05:45'	System	19 Dec 2020 07:05:48
	System	19 Dec 2020 07:05:48

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-12-27T14:43:16', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '0d9e50cf-3689-475d-9e3c-e537bdbe54b4' User entered 'No (N)'	System	27 Dec 2020 22:43:20
	System	27 Dec 2020 22:43:20

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-12-27T14:43:17', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '0d9e50cf-3689-475d-9e3c-e537bdb54b4'	System	27 Dec 2020 22:43:20
User entered 'No (N)'	System	27 Dec 2020 22:43:20

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2020-12-27T14:43:19', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '0d9e50cf-3689-475d-9e3c-e537bdbe54b4' User entered '27 Dec 2020 14:43:19'	System	27 Dec 2020 22:43:20
	System	27 Dec 2020 22:43:20

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-01-02T16:58:30', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '293f2e62-0862-4b73-b3bf-5d7e3ae19cb4' User entered 'No (N)'	System	03 Jan 2021 00:58:39
	System	03 Jan 2021 00:58:39

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-01-02T16:58:32', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '293f2e62-0862-4b73-b3bf-5d7e3ae19cb4' User entered 'No (N)'	System	03 Jan 2021 00:58:39

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-01-02T16:58:35', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '293f2e62-0862-4b73-b3bf-5d7e3ae19cb4' User entered '02 Jan 2021 16:58:35'	System	03 Jan 2021 00:58:39

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-01-08T06:03:32', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '7f107caa-02c9-4a8f-89f8-5e1c8723b272'	System	08 Jan 2021 14:03:38
User entered 'No (N)'	System	08 Jan 2021 14:03:38

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-01-08T06:03:33', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '7f107caa-02c9-4a8f-89f8-5e1c8723b272'	System	08 Jan 2021 14:03:38
User entered 'No (N)'	System	08 Jan 2021 14:03:38

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-01-08T06:03:35', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '7f107caa-02c9-4a8f-89f8-5e1c8723b272' User entered '08 Jan 2021 06:03:35'	System	08 Jan 2021 14:03:38
	System	08 Jan 2021 14:03:38

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-01-15T05:05:34', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '0301abef-8faf-49c5-8c25-8db8a09ce28a' User entered 'No (N)'	System	15 Jan 2021 13:05:41

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-01-15T05:05:36', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '0301abef-8faf-49c5-8c25-8db8a09ce28a' User entered 'No (N)'	System	15 Jan 2021 13:05:41

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-01-15T05:05:38', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '0301abef-8faf-49c5-8c25-8db8a09ce28a' User entered '15 Jan 2021 05:05:38'	System	15 Jan 2021 13:05:41
	System	15 Jan 2021 13:05:41

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-01-22T05:48:52', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '85b4902e-6a81-41da-ae90-f3377d82ca2f' User entered 'Yes (Y)'	System	22 Jan 2021 13:49:12
	System	22 Jan 2021 13:49:12

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-01-22T05:48:55', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '85b4902e-6a81-41da-ae90-f3377d82ca2f' User entered 'No (N)'	System	22 Jan 2021 13:49:12

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-01-22T05:48:59', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '85b4902e-6a81-41da-ae90-f3377d82ca2f' User entered 'No (N)'	System	22 Jan 2021 13:49:12

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-01-22T05:49:05', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '85b4902e-6a81-41da-ae90-f3377d82ca2f' User entered 'No (N)'	System	22 Jan 2021 13:49:12

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-01-22T05:49:07', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '85b4902e-6a81-41da-ae90-f3377d82ca2f' User entered '22 Jan 2021 05:49:07'	System	22 Jan 2021 13:49:12
	System	22 Jan 2021 13:49:12

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-01-29T07:00:43', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'b3020951-dd68-42c0-af43-6345636f2113'	System	29 Jan 2021 15:00:49
User entered 'No (N)'	System	29 Jan 2021 15:00:49

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-01-29T07:00:45', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'b3020951-dd68-42c0-af43-6345636f2113'	System	29 Jan 2021 15:00:49
User entered 'No (N)'	System	29 Jan 2021 15:00:49

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-01-29T07:00:47', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'b3020951-dd68-42c0-af43-6345636f2113' User entered '29 Jan 2021 07:00:47'	System	29 Jan 2021 15:00:49
	System	29 Jan 2021 15:00:49

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-02-05T05:36:37', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '19d3a6aa-91e2-404f-a08c-a9284ffcaeb' User entered 'No (N)'	System	05 Feb 2021 13:37:01
	System	05 Feb 2021 13:37:01

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-02-05T05:36:48', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '19d3a6aa-91e2-404f-a08c-a9284ffcaeb' User entered 'No (N)'	System	05 Feb 2021 13:37:01
	System	05 Feb 2021 13:37:01

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-02-05T05:36:58', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '19d3a6aa-91e2-404f-a08c-a9284ffcaeb' User entered '05 Feb 2021 05:36:58'	System	05 Feb 2021 13:37:01
	System	05 Feb 2021 13:37:01

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-02-12T05:36:19', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'fcab4d41-a88b-48ac-87e3-a8787461529e' User entered 'No (N)'	System	12 Feb 2021 13:36:26
	System	12 Feb 2021 13:36:26

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-02-12T05:36:21', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'fcab4d41-a88b-48ac-87e3-a8787461529e' User entered 'No (N)'	System	12 Feb 2021 13:36:26

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-02-12T05:36:24', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'fcab4d41-a88b-48ac-87e3-a8787461529e' User entered '12 Feb 2021 05:36:24'	System	12 Feb 2021 13:36:26
	System	12 Feb 2021 13:36:26

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-02-19T06:53:53', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '2d88ba12-5ac7-42a7-8399-a89e72bf07d3' User entered 'No (N)'	System	19 Feb 2021 14:53:59
	System	19 Feb 2021 14:53:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-02-19T06:53:54', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '2d88ba12-5ac7-42a7-8399-a89e72bf07d3' User entered 'No (N)'	System	19 Feb 2021 14:53:59
	System	19 Feb 2021 14:53:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-02-19T06:53:57', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '2d88ba12-5ac7-42a7-8399-a89e72bf07d3' User entered '19 Feb 2021 06:53:57'	System	19 Feb 2021 14:53:59
	System	19 Feb 2021 14:53:59

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-03-01T18:22:53', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'e2ed7fe0-5072-4a4a-b683-4583228ce74e' User entered 'No (N)'	System	02 Mar 2021 02:30:50
	System	02 Mar 2021 02:30:50

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-03-01T18:22:55', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'e2ed7fe0-5072-4a4a-b683-4583228ce74e' User entered 'No (N)'	System	02 Mar 2021 02:30:50
	System	02 Mar 2021 02:30:50

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-03-01T18:22:58', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: 'e2ed7fe0-5072-4a4a-b683-4583228ce74e' User entered '01 Mar 2021 18:22:58'	System	02 Mar 2021 02:30:50
	System	02 Mar 2021 02:30:50

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-03-05T13:35:25', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '20a37a73-fcc0-4350-a083-24dd256abd21' User entered 'No (N)'	System	05 Mar 2021 21:35:34
	System	05 Mar 2021 21:35:34

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-03-05T13:35:26', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '20a37a73-fcc0-4350-a083-24dd256abd21' User entered 'No (N)'	System	05 Mar 2021 21:35:34
	System	05 Mar 2021 21:35:34

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-03-05T13:35:28', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '20a37a73-fcc0-4350-a083-24dd256abd21' User entered '05 Mar 2021 13:35:28'	System	05 Mar 2021 21:35:34
	System	05 Mar 2021 21:35:34

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-03-12T05:16:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '048b836a-3d65-4a6e-a04a-ac84a9a541a5' User entered 'No (N)'	System	12 Mar 2021 13:16:14
	System	12 Mar 2021 13:16:14

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-03-12T05:16:03', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '048b836a-3d65-4a6e-a04a-ac84a9a541a5' User entered 'No (N)'	System	12 Mar 2021 13:16:14
	System	12 Mar 2021 13:16:14

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-03-12T05:16:07', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '048b836a-3d65-4a6e-a04a-ac84a9a541a5' User entered '12 Mar 2021 05:16:07'	System	12 Mar 2021 13:16:14
	System	12 Mar 2021 13:16:14

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-03-21T12:00:15', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '677b3278-83ef-4b98-8650-c07c646375ed' User entered 'No (N)'	System	21 Mar 2021 19:00:25
	System	21 Mar 2021 19:00:25

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-03-21T12:00:16', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '677b3278-83ef-4b98-8650-c07c646375ed' User entered 'No (N)'	System	21 Mar 2021 19:00:25
	System	21 Mar 2021 19:00:25

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-03-21T12:00:19', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '677b3278-83ef-4b98-8650-c07c646375ed' User entered '21 Mar 2021 12:00:19'	System	21 Mar 2021 19:00:25

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-03-26T06:54:44', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '6fe66300-f345-4751-84b4-531de3b5fb1b' User entered 'No (N)'	System	26 Mar 2021 13:54:50
	System	26 Mar 2021 13:54:50

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-03-26T06:54:45', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '6fe66300-f345-4751-84b4-531de3b5fb1b' User entered 'No (N)'	System	26 Mar 2021 13:54:50
	System	26 Mar 2021 13:54:50

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-03-26T06:54:47', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '6fe66300-f345-4751-84b4-531de3b5fb1b' User entered '26 Mar 2021 06:54:47'	System	26 Mar 2021 13:54:50
	System	26 Mar 2021 13:54:50

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-04-02T05:43:29-07:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '99264575-6b5f-4b73-9f6c-ef1f770f6ee4' User entered 'No (N)'	System	02 Apr 2021 12:43:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-04-02T05:43:30-07:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '99264575-6b5f-4b73-9f6c-ef1f770f6ee4' User entered 'No (N)'	System	02 Apr 2021 12:43:35
	System	02 Apr 2021 12:43:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-04-02T05:43:32-07:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '99264575-6b5f-4b73-9f6c-ef1f770f6ee4'	System	02 Apr 2021 12:43:35
User entered '02 Apr 2021 05:43:32'	System	02 Apr 2021 12:43:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-04-10T08:42:35-07:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '44f660a2-c867-4684-aba1-f193876082aa' User entered 'No (N)'	System	10 Apr 2021 15:42:43
	System	10 Apr 2021 15:42:43

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-04-10T08:42:36-07:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '44f660a2-c867-4684-aba1-f193876082aa' User entered 'No (N)'	System	10 Apr 2021 15:42:43

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-04-10T08:42:38-07:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '44f660a2-c867-4684-aba1-f193876082aa' User entered '10 Apr 2021 08:42:38'	System	10 Apr 2021 15:42:43
	System	10 Apr 2021 15:42:43

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-04-16T05:58:49-07:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1b11ffa7-3b3f-49f8-8747-3c5073d115f2'	System	16 Apr 2021 12:59:00
User entered 'No (N)'	System	16 Apr 2021 12:59:00

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-04-16T05:58:51-07:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1b11ffa7-3b3f-49f8-8747-3c5073d115f2'	System	16 Apr 2021 12:59:00
User entered 'No (N)'	System	16 Apr 2021 12:59:00

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-04-16T05:58:53-07:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1b11ffa7-3b3f-49f8-8747-3c5073d115f2'	System	16 Apr 2021 12:59:00
User entered '16 Apr 2021 05:58:53'	System	16 Apr 2021 12:59:00

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-04-24T15:11:42-07:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '93f9a677-32ee-4586-95a7-c6fdb3cfba19'	System	24 Apr 2021 22:11:49
User entered 'No (N)'	System	24 Apr 2021 22:11:49

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-04-24T15:11:44-07:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '93f9a677-32ee-4586-95a7-c6fdb3cfba19'	System	24 Apr 2021 22:11:49
User entered 'No (N)'	System	24 Apr 2021 22:11:49

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-04-24T15:11:45-07:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '93f9a677-32ee-4586-95a7-c6fdb3cfba19' User entered '24 Apr 2021 15:11:45'	System	24 Apr 2021 22:11:49
	System	24 Apr 2021 22:11:49

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-04-30T07:53:17-07:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '61a490d4-4d12-4b42-bfcb-5d8092798cf4' User entered 'No (N)'	System	30 Apr 2021 14:53:24
	System	30 Apr 2021 14:53:24

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

Have you been exposed to someone with 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 (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-04-30T07:53:18-07:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '61a490d4-4d12-4b42-bfcb-5d8092798cf4'	System	30 Apr 2021 14:53:24
User entered 'No (N)'	System	30 Apr 2021 14:53:24

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-04-30T07:53:20-07:00', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '61a490d4-4d12-4b42-bfcb-5d8092798cf4' User entered '30 Apr 2021 07:53:20'	System	30 Apr 2021 14:53:24
	System	30 Apr 2021 14:53:24

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 06:54:35

US3462421

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:54:35
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 06:54:35

US3462421

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:41:44

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 07:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-03-01T18:23:10', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1c009da5-f871-406d-b2ef-d68e1c6118bf'	System	02 Mar 2021 02:31:04
User entered 'No (N)'	System	02 Mar 2021 02:31:04

US3462421

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:41:44

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:35:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (85AEFFFB-B3C9-4FCE-A11A-D24E0BE79147)', Time: '2021-03-01T18:23:13', User OID: 'PatientReportedOutcome (US3462421)', ODM File OID: '1c009da5-f871-406d-b2ef-d68e1c6118bf' User entered '01 Mar 2021 18:23:13'	System	02 Mar 2021 02:31:04
	System	02 Mar 2021 02:31:04

US3462421

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
DataPoint Verified.		14 Apr 2021 17:50:18
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:39:09

US3462421

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
DataPoint Verified.		14 Apr 2021 17:50:18
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:39:09

US3462421

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
DataPoint Verified.		14 Apr 2021 17:50:18
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:39:09

US3462421

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
DataPoint Verified.		14 Apr 2021 17:50:18
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:39:09

US3462421

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
DataPoint Verified.		14 Apr 2021 17:49:54
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:38:40

US3462421

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:58:22
User entered 'I'	System	02 Apr 2021 18:38:40

US3462421

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:37:47
DataPoint Verified.		14 Apr 2021 17:43:06
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:39:30

US3462421

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:37:47
DataPoint Verified.		14 Apr 2021 17:43:06
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).		05 Apr 2021 14:49:12
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Confirmed' (Site from System).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:39:44
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	02 Apr 2021 18:39:30
User entered '21 Dec 2020'	(b) (4), (b) (6)	02 Apr 2021 18:39:30

US3462421

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:37:47
DataPoint Verified.		14 Apr 2021 17:43:06
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:39:30

US3462421

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:37:47
DataPoint Verified.		14 Apr 2021 17:43:06
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:39:30

US3462421

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:37:47
DataPoint Verified.		14 Apr 2021 17:39:41
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:38:53

US3462421

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:37:47
User entered 'I'	System	02 Apr 2021 18:38:53

US3462421

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:37:47
DataPoint Verified.		14 Apr 2021 17:44:20
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:46:25

US3462421

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:37:47
DataPoint Verified.		14 Apr 2021 17:44:20
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered '3 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:46:25

US3462421

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:37:47
DataPoint Verified.		14 Apr 2021 17:44:20
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:46:25

US3462421

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:37:47
DataPoint Verified.		14 Apr 2021 17:44:20
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:46:25

US3462421

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:37:47
DataPoint Verified.		14 Apr 2021 17:43:16
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:46:33

US3462421

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:37:47
User entered 'I'	System	02 Apr 2021 18:46:33

US3462421

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:37:47
DataPoint Verified.		14 Apr 2021 17:49:37
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:48:53

US3462421

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:37:47
DataPoint Verified.		14 Apr 2021 17:49:37
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23MAR2021 is recorded under Visit 04 Day 209 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you ' (Site from DM).		08 Apr 2021 10:45:03
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23MAR2021 is recorded under Visit 04 Day 209 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you ' answered with 'updated data' (Site from DM).		05 Apr 2021 17:26:40
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23MAR2021 is recorded under Visit 04 Day 209 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you ' (Site from DM).		05 Apr 2021 13:12:28
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:48:53

US3462421

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:37:47
DataPoint Verified.		14 Apr 2021 17:49:37
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:48:53

US3462421

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:37:47
DataPoint Verified.		14 Apr 2021 17:49:37
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:48:53

US3462421

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:37:47
DataPoint Verified.		14 Apr 2021 17:46:28
User signature succeeded.	Gregg Lucksinger (b) (4)	02 Apr 2021 20:13:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:50:04

US3462421

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:37:47
User entered 'I'	System	02 Apr 2021 18:50:04

US3462421

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:54:51
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:24:52

US3462421

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:54:51
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:24:52

US3462421

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:54:51
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:24:52

US3462421

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
User entered 'VISIT4'	System	05 Apr 2021 17:24:52

US3462421

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:55:04
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:25:48

US3462421

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:55:04
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:25:48

US3462421

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:55:04
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:25:48

US3462421

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
User entered empty.	System	05 Apr 2021 17:25:48

US3462421

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:55:04
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:25:48

US3462421

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:55:04
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:25:48

US3462421

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:55:04
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:25:48

US3462421

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:55:04
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:25:48

US3462421

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
User entered empty.	System	05 Apr 2021 17:25:48

US3462421

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:55:04
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:25:48

US3462421

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
User entered empty.	System	05 Apr 2021 17:25:48

US3462421

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:55:04
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:25:48

US3462421

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
User entered empty.	System	05 Apr 2021 17:25:48

US3462421

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:55:04
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:25:48

US3462421

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
User entered empty.	System	05 Apr 2021 17:25:48

US3462421

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30

US3462421

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30

US3462421

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:54:40
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:25:58

US3462421

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:54:40
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:25:58

US3462421

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:53:49
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:26:08

US3462421

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:53:49
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:26:08

US3462421

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:53:49
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '09:10'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:26:08

US3462421

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
User entered '23 Mar 2021 09:10'	System	05 Apr 2021 17:26:08

US3462421

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
DataPoint Verified.		14 Apr 2021 17:53:14
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:26:11

US3462421

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:33:30
User entered 'I'	System	05 Apr 2021 17:26:11

US3462421

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

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:38:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	17 Jan 2021 20:22:00

US3462421

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

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:38:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '13 Jan 2021'	(b) (4)	
	(b) (4), (b) (6)	17 Jan 2021 20:22:00

US3462421

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

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

[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 19:01:26
DataPoint Verified.		14 Apr 2021 17:38:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:22:00

US3462421

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

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'UNBLND_DECIDE'	System	17 Jan 2021 20:22:00

US3462421

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:44

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:37:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:22:49

US3462421

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:44

[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 19:01:26
DataPoint Verified.		14 Apr 2021 17:37:57
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:37:11
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:44:22

US3462421

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:44

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:37:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:22:49

US3462421

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:44

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:37:57
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:37:11
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:44:22

US3462421

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:44

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:37:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:22:49

US3462421

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:44

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:37:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:22:49

US3462421

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:44

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:37:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 04:30:41
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	17 Jan 2021 20:22:49

US3462421

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:44

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:37:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 04:30:41
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	17 Jan 2021 20:22:49

US3462421

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:44

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:37:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:22:49

US3462421

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:44

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered '1'	System	17 Jan 2021 20:22:49

US3462421

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

Form: Unblinding

Generated On: 09 Jun 2021 17:41:44

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'I'	System	17 Jan 2021 20:22:49

US3462421

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '171' cm	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '70' kg	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered '23.93899'	System	17 Jan 2021 20:25:04
DataPoint set to visible.	System	17 Jan 2021 20:22:49

US3462421

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '171' cm	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '70' kg	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered '23.93899'	System	17 Jan 2021 20:25:04
DataPoint set to visible.	System	17 Jan 2021 20:22:49

US3462421

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User accepted default value 'Pre-Dose (PREDOSE)'		17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '04:55'	(b) (4)	
	(b) (4), (b) (6)	17 Jan 2021 20:25:04

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered '13 Jan 2021 04:55'	System	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '98.0' F	(b) (4)	
	(b) (4), (b) (6)	17 Jan 2021 20:25:04

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'Tympanic'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '67'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'bpm'	System	17 Jan 2021 20:25:04

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '18'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'breaths/min'	System	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '122'	(b) (4)	
	(b) (4), (b) (6)	17 Jan 2021 20:25:04

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'mmHg'	System	17 Jan 2021 20:25:04

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '70'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'mmHg'	System	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '171' cm	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '70' kg	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered '23.93899'	System	17 Jan 2021 20:25:04
DataPoint set to visible.	System	17 Jan 2021 20:22:49

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User accepted default value 'Post-Dose (POSTDOSE)'		17 Jan 2021 20:25:04

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	17 Jan 2021 20:25:04

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '17:56'	(b) (4)	
	(b) (4), (b) (6)	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered '13 Jan 2021 17:56'	System	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'Tympanic'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '72'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'bpm'	System	17 Jan 2021 20:25:04

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '14'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'breaths/min'	System	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '103'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'mmHg'	System	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:39:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '63'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:25:04

US3462421

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'mmHg'	System	17 Jan 2021 20:25:04

US3462421

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:37:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:27:18

US3462421

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:37:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:27:18

US3462421

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:37:38
User closed query 'Per CDM: Per protocol, a negative pregnancy test is required for female participants of childbearing potential prior to receiving any study drug, however 'Was the pregnancy test performed?' is NO. Please review and clarify.' (Site from DM). User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
Query 'Per CDM: Per protocol, a negative pregnancy test is required for female participants of childbearing potential prior to receiving any study drug, however 'Was the pregnancy test performed?' is NO. Please review and clarify.' answered with 'updated data' (Site from DM). User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 20:55:49
		06 Apr 2021 20:55:31
User opened query 'Per CDM: Per protocol, a negative pregnancy test is required for female participants of childbearing potential prior to receiving any study drug, however 'Was the pregnancy test performed?' is NO. Please review and clarify.' (Site from DM). User entered 'No (N)'		20 Jan 2021 09:26:44
		17 Jan 2021 20:29:33

US3462421

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:37:38
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:55:31
User entered empty.		17 Jan 2021 20:29:33

US3462421

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:37:38
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'Urine (URINE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:55:31
User entered empty.		17 Jan 2021 20:29:33

US3462421

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:37:38
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:55:31
User entered empty.		17 Jan 2021 20:29:33

US3462421

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:37:38
User closed query 'Per CDM: A Yes or no response is required for this field. Please review and update as appropriate.' (Site from DM).		07 Apr 2021 09:03:17
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
Query 'Per CDM: A Yes or no response is required for this field. Please review and update as appropriate.' answered with 'updated data' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:56:14
User entered 'No (N)' reason for change: Data Entry Error		06 Apr 2021 20:55:31
User opened query 'Per CDM: A Yes or no response is required for this field. Please review and update as appropriate.' (Site from DM).		02 Mar 2021 15:42:20
User entered empty.		17 Jan 2021 20:29:33

US3462421

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:37:38
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	17 Jan 2021 20:29:33

US3462421

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:37:38
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	17 Jan 2021 20:29:33

US3462421

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered empty.	System	17 Jan 2021 20:29:33

US3462421

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:35:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:30:31

US3462421

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:35:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	17 Jan 2021 20:30:31

US3462421

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:35:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered empty.	(b) (4), (b) (6)	17 Jan 2021 20:30:31

US3462421

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'mRNA-1273'	System	17 Jan 2021 20:30:31
DataPoint set to visible.	System	17 Jan 2021 20:22:49

US3462421

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:35:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:30:31

US3462421

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:35:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '17:26'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:30:31

US3462421

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered '13 Jan 2021 17:26'	System	17 Jan 2021 20:30:31

US3462421

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:35:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:30:31

US3462421

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:35:33
User entered 'ONCE'	System	17 Jan 2021 20:30:31

US3462421

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

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered 'INTRAMUSCULAR'	System	17 Jan 2021 20:30:31

US3462421

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:35:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:33:21

US3462421

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:35:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '13 Jan 2021'	(b) (4)	
	(b) (4), (b) (6)	17 Jan 2021 20:33:21

US3462421

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:35:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '16:50'	(b) (4)	
	(b) (4), (b) (6)	17 Jan 2021 20:33:21

US3462421

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered '13 Jan 2021 16:50'	System	17 Jan 2021 20:33:21

US3462421

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:41:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:34:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:33:39

US3462421

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:41:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:34:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:33:39

US3462421

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:34:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '16:33'	(b) (4)	
	(b) (4), (b) (6)	17 Jan 2021 20:33:39

US3462421

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered '13 Jan 2021 16:33'	System	17 Jan 2021 20:33:39

US3462421

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

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
DataPoint Verified.		14 Apr 2021 17:34:30
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Jan 2021 20:33:48

US3462421

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

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:01:26
User entered '1'	System	17 Jan 2021 20:33:48

US3462421

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:27:48

US3462421

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Apr 2021 21:09:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:16:34
User closed query 'Per source worksheet identified as Dose 1: Day 8 dated 20-JAN-2021 for Safety Call and EDC has 8-FEB-2021, please clarify?' (Site from CRA).		19 Apr 2021 19:16:29
Query 'Per source worksheet identified as Dose 1: Day 8 dated 20-JAN-2021 for Safety Call and EDC has 8-FEB-2021, please clarify?' answered with 'DATA UPDATED ' (Site from CRA).		15 Apr 2021 21:00:04
DataPoint Un-verified.		15 Apr 2021 20:59:43
Signature has been broken.		15 Apr 2021 20:59:43
User entered '20 Jan 2021' reason for change: Data Entry Error		15 Apr 2021 20:59:43
DataPoint Verified.		14 Apr 2021 17:53:03
User opened query 'Per source worksheet identified as Dose 1: Day 8 dated 20-JAN-2021 for Safety Call and EDC has 8-FEB-2021, please clarify?' (Site from CRA).		14 Apr 2021 17:52:57
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		06 Apr 2021 12:28:26
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'date is correct' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:28:01

US3462421

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). User entered '8 Feb 2021'	System (b) (4), (b) (6)	05 Apr 2021 17:27:48 05 Apr 2021 17:27:48

US3462421

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:27:48

US3462421

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:27:48

US3462421

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:51:21
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:27:53

US3462421

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered 'I'	System	05 Apr 2021 17:27:53

US3462421

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered '1'	System	05 Apr 2021 17:27:53
DataPoint set to visible.	System	05 Apr 2021 17:27:53

US3462421

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:29:10
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:28:18

US3462421

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:29:10
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:28:18

US3462421

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:29:10
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:28:18

US3462421

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered 'OLD29'	System	05 Apr 2021 17:28:18

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User accepted default value 'Pre-Dose (PREDOSE)'		05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '12:30'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered '12 Feb 2021 12:30'	System	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'tympanic'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '72'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered 'bpm'	System	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered 'breaths/min'	System	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '110'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered 'mmHg'	System	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '74'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered 'mmHg'	System	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User accepted default value 'Post-Dose (POSTDOSE)'		05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '14:05'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered '12 Feb 2021 14:05'	System	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'tympanic'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '73'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered 'bpm'	System	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '14'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered 'breaths/min'	System	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '141'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered 'mmHg'	System	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:30:02
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '89'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered 'mmHg'	System	05 Apr 2021 17:30:28

US3462421

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User closed query 'Per 12-FEB-2021 source worksheet, Physical Exam is lined out. Please clarify if PE was performed?' (Site from CRA). DataPoint Verified.		19 Apr 2021 19:15:41 19 Apr 2021 19:15:39
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:13
Query 'Per 12-FEB-2021 source worksheet, Physical Exam is lined out. Please clarify if PE was performed?' answered with 'Updated Data' (Site from CRA). DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:58:56 15 Apr 2021 20:58:00
Signature has been broken.		15 Apr 2021 20:58:00
User entered 'No (N)' reason for change: Data Entry Error DataPoint Verified.		15 Apr 2021 20:58:00 14 Apr 2021 17:28:39
User opened query 'Per 12-FEB-2021 source worksheet, Physical Exam is lined out. Please clarify if PE was performed?' (Site from CRA). Query 'Per 12-FEB-2021 source worksheet, Physical Exam is lined out. Please clarify?' canceled (Site from CRA). User opened query 'Per 12-FEB-2021 source worksheet, Physical Exam is lined out. Please clarify?' (Site from CRA). User signature succeeded.		14 Apr 2021 17:28:37 14 Apr 2021 17:28:07 14 Apr 2021 17:27:58
User entered 'Yes (Y)'	Gregg Lucksinger (b) (4) (b) (4) (b) (4), (b) (6)	05 Apr 2021 18:21:02 05 Apr 2021 17:30:38

US3462421

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		19 Apr 2021 19:15:43
User signature succeeded.	Gregg Lucksinger (b) (4)	15 Apr 2021 21:14:13
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:58:00
Signature has been broken.		15 Apr 2021 20:58:00
User entered empty; reason for change Data Entry Error		15 Apr 2021 20:58:00
DataPoint Verified.		14 Apr 2021 17:28:39
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:38

US3462421

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:28:58
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:48

US3462421

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:28:58
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:48

US3462421

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:28:58
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:48

US3462421

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:28:58
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:48

US3462421

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:28:58
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:48

US3462421

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:28:58
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:48

US3462421

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:28:58
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:30:48

US3462421

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered empty.	System	05 Apr 2021 17:30:48

US3462421

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:27:19
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:05

US3462421

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:27:19
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:05

US3462421

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:27:19
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:05

US3462421

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered 'mRNA-1273'	System	05 Apr 2021 17:31:05
DataPoint set to visible.	System	05 Apr 2021 17:27:53

US3462421

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:27:19
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:05

US3462421

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:27:19
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '13:35'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:05

US3462421

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered '12 Feb 2021 13:35'	System	05 Apr 2021 17:31:05

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:27:19
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:05

US3462421

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:27:19
User entered 'ONCE'	System	05 Apr 2021 17:31:05

US3462421

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered 'INTRAMUSCULAR'	System	05 Apr 2021 17:31:05

US3462421

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:26:19
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:12

US3462421

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered 'I'	System	05 Apr 2021 17:31:12

US3462421

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:51:12
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:35

US3462421

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:51:12
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:35

US3462421

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:51:12
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:35

US3462421

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:51:12
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:35

US3462421

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:50:27
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:43

US3462421

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered 'I'	System	05 Apr 2021 17:31:43

US3462421

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:33:49
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:52

US3462421

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:33:49
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:52

US3462421

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:33:49
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:52

US3462421

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered 'OLD57'	System	05 Apr 2021 17:31:52

US3462421

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:34:00
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:58

US3462421

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:34:00
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:58

US3462421

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:34:00
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:58

US3462421

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered empty.	System	05 Apr 2021 17:31:58

US3462421

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:34:00
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:58

US3462421

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:34:00
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:58

US3462421

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:34:00
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:58

US3462421

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:34:00
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:58

US3462421

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered empty.	System	05 Apr 2021 17:31:58

US3462421

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:34:00
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:58

US3462421

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered empty.	System	05 Apr 2021 17:31:58

US3462421

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:34:00
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:58

US3462421

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered empty.	System	05 Apr 2021 17:31:58

US3462421

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:34:00
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:31:58

US3462421

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered empty.	System	05 Apr 2021 17:31:58

US3462421

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21

US3462421

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21

US3462421

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:33:37
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:32:03

US3462421

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:33:37
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:32:03

US3462421

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:33:27
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:32:17

US3462421

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:33:27
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:32:17

US3462421

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
DataPoint Verified.		14 Apr 2021 17:33:27
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 18:21:02
User entered '09:10'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:32:17

US3462421

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:57:21
User entered '23 Mar 2021 09:10'	System	05 Apr 2021 17:32:17

US3462421

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:41:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:05:57
DataPoint Verified.		14 Apr 2021 17:26:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:16:52

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 19:41:12
User entered 'USA-US093-2021-mRNA-1273-P301000004'	System	03 Feb 2021 19:41:08
User entered 'New'	(b) (4), (b) (6)	03 Feb 2021 19:41:08

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Pregnancy, labour, delivery and postpartum conditions, HLT: Normal pregnancy, labour and delivery, PT: Pregnancy, LLT: Pregnancy - version MedDRA\\23.0.	Coder Import (b) (4)	08 Feb 2021 00:14:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Feb 2021 00:14:48
Data point term sent to Coder	System	02 Feb 2021 23:18:20
User entered 'Pregnancy on the study'	Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '21 Jan 2021'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '23 Jan 2021'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:45:11
User entered 'No (N)'	Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '1' reason for change: Data Entry Error	(b) (4)	02 Feb 2021 23:45:11
User entered '0'	Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'Not Related (NOT RELATED)'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'Not Related (NOT RELATED)'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User closed query 'PV Query: As the subject experienced pregnancy, please consider updating action taken for the events to drug withdrawn.' (Site from Safety).		07 Apr 2021 13:21:30
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
Query 'PV Query: As the subject experienced pregnancy, please consider updating action taken for the events to drug withdrawn.' answered with 'their was no action taken as she was only pregnant for a short time and when she informed PI she had already had a miscarriage ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:50:54
User opened query 'PV Query: As the subject experienced pregnancy, please consider updating action taken for the events to drug withdrawn.' (Site from Safety).		12 Feb 2021 22:05:12
User entered 'None (NONE)'	Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'I'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

US3462421

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

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Folder: Adverse Events

Form: Adverse Events (1)

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4) System	02 Feb 2021 23:47:18
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	02 Feb 2021 23:47:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT IS A 28 YEAR OLD FEMALE WHO COMPLETED OPEN-LABEL VISIT 1 AND RECEIVED FIRST DOSE OF OPEN-LABEL IP ON 13JAN2021. SUBJECT HAD A NEGATIVE PREGNANCY TEST AT THIS VISIT PRIOR TO DOSING. SUBJECT REPORTED THAT HER LAST MENSTRUAL CYCLE PRIOR TO THIS VISIT STARTED ON APPROXIMATELY 16DEC2020. SUBJECT STATED THAT SHE HAS VERY REGULAR CYCLES AND THEREFORE, WHEN SHE HAD NOT STARTED HER NEXT MENSTRUAL CYCLE (EXPECTED TO START ON OR AROUND 16-18JAN2021), SUBJECT PERFORMED AN AT HOME PREGNANCY TEST. TEST WAS CONDUCTED ON 21JAN2021 AND WAS POSITIVE. ON 23JAN2021, SUBJECT REPORTED THAT SHE STARTED BLEEDING AND INITIALLY THOUGHT THAT SHE MIGHT BE STARTING HER NEXT MENSES, HOWEVER, SUBJECT NOTICED THAT SHE HAD CLOTS ALONG WITH HER NORMAL BLEEDING. SUBJECT REPORTED THAT SHE CONTINUED TO BLEED FOR THE NEXT 6 DAYS WITH BLEEDING STOPPING ON 29JAN2021. SUBJECT STATED THAT SHE HAS NOT TAKEN ADDITIONAL PREGNANCY TEST, BUT BELIEVES THAT SHE IS NO LONGER PREGNANT. SUBJECT REPORTED MINIMAL SYMPTOMS AND FELT STABLE. ALL DETAILS WERE PROVIDED VIA SUBJECT PHONE CALL WITH SITE ON 02FEB2021 AS SUBJECT HAS NOT YET SEEN A DOCTOR. SUBJECT STATED THAT SHE DOES HAVE A VISIT SCHEDULED FOR LATER THIS WEEK. PI EVALUATED THIS SAE AND DETERMINED THAT SINCE IP CAUSALITY CANNOT BE RULED OUT AND DUE TO TEMPOROL RELATIONSHIP, WE WILL LIST THIS SAE AS RELATED FOR NOW.' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	02 Feb 2021 23:47:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	02 Feb 2021 23:45:11
User entered empty.	Danuel Hamlin (b) (4)	02 Feb 2021 23:18:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 23:45:11
User entered '0'	System	02 Feb 2021 23:18:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Feb 2021 23:18:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:43:28
User entered 'USA-US093-2021-mRNA-1273-P301000004'		03 Feb 2021 19:42:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Abortions and stillbirth, HLT: Abortions spontaneous, PT: Abortion spontaneous, LLT: Miscarriage - version MedDRA\\23.0.	Coder Import (b) (4)	02 Feb 2021 23:32:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Feb 2021 23:32:33
Data point term sent to Coder	System	02 Feb 2021 23:31:25
User entered 'Miscarriage'	Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '23 Jan 2021'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '23 Jan 2021'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

US3462421

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

US3462421

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty.	Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

US3462421

Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

US3462421

Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

US3462421

Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'I'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'Related (RELATED)'	Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'Not Related (NOT RELATED)'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User closed query 'PV Query: As the subject experienced pregnancy, please consider updating action taken for the events to drug withdrawn.' (Site from Safety).		07 Apr 2021 13:22:27
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
Query 'PV Query: As the subject experienced pregnancy, please consider updating action taken for the events to drug withdrawn.' answered with 'No action was taken by the time subject informed us about pregnancy and miscarriage she was in-between doses ' (Site from Safety).	(b) (4) (d) (4), (b) (6)	06 Apr 2021 21:02:18
User opened query 'PV Query: As the subject experienced pregnancy, please consider updating action taken for the events to drug withdrawn.' (Site from Safety).		12 Feb 2021 22:05:26
User entered 'None (NONE)'	Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM). User signature succeeded.	(b) (4)	07 Apr 2021 08:33:14
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'Per PI and Subject no meds needed for this AE ' (Site from DM). User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM). User entered 'I'	Gregg Lucksinger (b) (4) (b) (4) (b) (4), (b) (6)	06 Apr 2021 22:56:16 06 Apr 2021 21:03:39 23 Feb 2021 01:56:34
	Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered '0'	Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

US3462421

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

US3462421

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

US3462421

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:25:18
User closed query 'PV Query: Please provide further details about the events after the subject's physician visit, including the estimated date of conception, gestational age at the time of miscarriage, etc. Once further details are available, please consider reassessing the causal relationship between the study drug and the event of miscarriage.' (Site from Safety)		07 Apr 2021 13:22:24
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).		07 Apr 2021 13:22:23
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).		07 Apr 2021 13:22:21
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		07 Apr 2021 13:22:19
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:56:16
Query 'PV Query: Please provide further details about the events after the subject's physician visit, including the estimated date of conception, gestational age at the time of miscarriage, etc. Once further details are available, please consider reassessing the causal relationship between the study drug and the event of miscarriage.' answered with 'Per PI , Email was sent to Moderna and subject is okay to continue with study ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:05:20
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'N/A' (Site from Safety).		06 Apr 2021 21:04:44

US3462421

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'No con meds recived' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 21:04:31
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'none' (Site from Safety).		06 Apr 2021 21:04:21
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		12 Feb 2021 22:06:03
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).		12 Feb 2021 22:05:56
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).		12 Feb 2021 22:05:49
User opened query 'PV Query: Please provide further details about the events after the subject's physician visit, including the estimated date of conception, gestational age at the time of miscarriage, etc. Once further details are available, please consider reassessing the causal relationship between the study drug and the event of miscarriage.' (Site from Safety).		12 Feb 2021 22:05:37

US3462421

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT IS A 28 YEAR OLD FEMALE WHO COMPLETED OPEN-LABEL VISIT 1 AND RECEIVED FIRST DOSE OF OPEN-LABEL IP ON 13JAN2021. SUBJECT HAD A NEGATIVE PREGNANCY TEST AT THIS VISIT PRIOR TO DOSING. SUBJECT REPORTED THAT HER LAST MENSTRUAL CYCLE PRIOR TO THIS VISIT STARTED ON APPROXIMATELY 16DEC2020. SUBJECT STATED THAT SHE HAS VERY REGULAR CYCLES AND THEREFORE, WHEN SHE HAD NOT STARTED HER NEXT MENSTRUAL CYCLE (EXPECTED TO START ON OR AROUND 16-18JAN2021), SUBJECT PERFORMED AN AT HOME PREGNANCY TEST. TEST WAS CONDUCTED ON 21JAN2021 AND WAS POSITIVE. ON 23JAN2021, SUBJECT REPORTED THAT SHE STARTED BLEEDING AND INITIALLY THOUGHT THAT SHE MIGHT BE STARTING HER NEXT MENSES, HOWEVER, SUBJECT NOTICED THAT SHE HAD CLOTS ALONG WITH HER NORMAL BLEEDING. SUBJECT REPORTED THAT SHE CONTINUED TO BLEED FOR THE NEXT 6 DAYS WITH BLEEDING STOPPING ON 29JAN2021. SUBJECT STATED THAT SHE HAS NOT TAKEN ADDITIONAL PREGNANCY TEST, BUT BELIEVES THAT SHE IS NO LONGER PREGNANT. SUBJECT REPORTED MINIMAL SYMPTOMS AND FELT STABLE. ALL DETAILS WERE PROVIDED VIA SUBJECT PHONE CALL WITH SITE ON 02FEB2021 AS SUBJECT HAS NOT YET SEEN A DOCTOR. SUBJECT STATED THAT SHE DOES HAVE A VISIT SCHEDULED FOR LATER THIS WEEK. PI EVALUATED THIS SAE AND DETERMINED THAT SINCE IP CAUSALITY CANNOT BE RULED OUT AND DUE TO TEMPOROL RELATIONSHIP, WE WILL LIST THIS SAE AS RELATED FOR NOW.' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	02 Feb 2021 23:40:02

US3462421

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject is a 28 year old female who completed Open-Label Visit 1 and received first dose of open-label IP on 13JAN2021. Subject had a negative pregnancy test at this visit prior to dosing. Subject reported that her last menstrual cycle prior to this visit started on approximately 16DEC2020. Subject stated that she has very regular cycles and therefore, when she had not started her next menstrual cycle (expected to start on or around 16-18JAN2021), subject performed an at home pregnancy test. Test was conducted on 21JAN2021 and was positive. On 23JAN2021, subject reported that she started bleeding and initially thought that she might be starting her next menses, however, subject noticed that she had clots along with her normal bleeding. Subject reported that she continued to bleed for the next 6 days with bleeding stopping on 29JAN2021. Subject stated that she has not taken additional pregnancy test, but believes that she is no longer pregnant. Subject reported minimal symptoms and felt stable. All details were provided via subject phone call with site on 02FEB2021 as subject has not yet seen a doctor. Subject stated that she does have a visit scheduled for later this week.'	Danuel Hamlin (b) (4)	02 Feb 2021 23:30:55

US3462421

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 23:30:55

US3462421

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Feb 2021 23:30:55

US3462421

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:41:44

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 20:56:19
User entered 'No (N)'		12 Sep 2020 20:01:09

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'USA-US093-2021-MRNA-1273-P301000004'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'Yes (Y)'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'No (N)'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'No (N)'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'No (N)'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'No (N)'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'No (N)'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'Yes (Y)'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'Edward'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'Kerwin'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'US'	(b) (4) System	03 Feb 2021 19:43:50

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'I'	(b) (4) System	03 Feb 2021 19:43:50

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'USA-US093-2021-MRNA-1273-P301000004'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'Yes (Y)'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'No (N)'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'No (N)'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'No (N)'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'No (N)'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'No (N)'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'Yes (Y)'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'Edward'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 19:43:42
User entered 'Kerwin'	System	03 Feb 2021 19:41:08

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'US'	(b) (4) System	03 Feb 2021 19:43:50

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'I'	(b) (4) System	03 Feb 2021 19:43:50

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:41:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered '03/Feb/2021 19:43'	(b) (4) System	03 Feb 2021 19:43:50

US3462421

Folder: SAE USA-US093-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:41:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:39:28
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:46:57
User entered 'I'	(b) (4), (b) (6)	03 Feb 2021 19:43:50