

US3402430 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:38:39

All time stamps listed in this document are displayed in GMT

US3402430

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

[Participant ID](#)

US3402430

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

US3402430

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 08 Mar 2021 22:45:54

Generated On: 11 Aug 2021 22:38:39

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

Visit date (dd MMM yyyy)	22 AUG 2020
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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	SCRN
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US3402430

Folder: Screening

Form: Demographics

Data signed: (b) (4) 08 Mar 2021 22:45:53

Generated On: 11 Aug 2021 22:38:39

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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) 08 Mar 2021 22:45:53

Generated On: 11 Aug 2021 22:38:39

Date of Informed Consent (<i>dd MMM yyyy</i>)	22 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 08 Mar 2021 22:45:53

Generated On: 11 Aug 2021 22:38:39

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 08 Mar 2021 22:45:53

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Mar 2021 22:45:53

Generated On: 11 Aug 2021 22:38:39

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Mar 2021 22:45:53

Generated On: 11 Aug 2021 22:38:39

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN JAN 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Mar 2021 22:45:53

Generated On: 11 Aug 2021 22:38:39

Condition	TOTAL HYSTERECTOMY
Start date (dd MMM yyyy)	UN JAN 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JAN 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Mar 2021 22:45:53

Generated On: 11 Aug 2021 22:38:39

Condition	GASTROESAPHEGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Mar 2021 22:45:54

Generated On: 11 Aug 2021 22:38:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	22 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:26 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 13:26
Height (<i>xxx.x</i>)	162.3 cm
Weight (<i>xxx.x</i>)	74.4 kg
BMI (<i>xxx.x</i>)	28.24463 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) 08 Mar 2021 22:45:53

Generated On: 11 Aug 2021 22:38:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 AUG 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) 08 Mar 2021 22:45:53

Generated On: 11 Aug 2021 22:38:39

Date of assessment (dd MMM yyyy) 22 AUG 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) UN JAN 2012

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: Risk of Exposure

Data signed: (b) (4) 08 Mar 2021 22:45:53

Generated On: 11 Aug 2021 22:38:39

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 08 Mar 2021 22:45:53

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

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

What was the participant's randomization number? 107416

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

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)	22 AUG 2020
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 13:26
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 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) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

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)	22 AUG 2020
Time of assessment (00:00-23:59)	14:27 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 14:27
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 22 AUG 2020

What was the treatment time? (00:00-23:59) 13:54 (24 HR)

Treatment Date and Time (derived) 22 AUG 2020 13:54

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 AUG 2020

Collection time (00:00-23:59)

13:42 (24 HR)

Collection date and time (derived)

22 AUG 2020 13:42

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Collection date (dd MMM yyyy)			22 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:39	22 AUG 2020 13:39
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 14:28

PC Open Date & Time

22 AUG 2020 14:14

PC Close Date & Time

22 AUG 2020 16:44

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp 22 AUG 2020 19:56

PC Open Date & Time 22 AUG 2020 17:39

PC Close Date & Time 23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:39

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

23 AUG 2020 20:48

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:39

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

97.2 °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

24 AUG 2020 19:13

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:39

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

97.2 °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

25 AUG 2020 19:08

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:39

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

96.8 °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

26 AUG 2020 20:22

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:39

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

27 AUG 2020 18:21

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:39

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

96.3 °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

28 AUG 2020 21:56

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 14:30

PC Open Date & Time

22 AUG 2020 14:14

PC Close Date & Time

22 AUG 2020 16:44

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 19:57

PC Open Date & Time

22 AUG 2020 17:39

PC Close Date & Time

23 AUG 2020 11:59

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:39

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

23 AUG 2020 20:48

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:39

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

24 AUG 2020 19:14

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:39

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

25 AUG 2020 19:09

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:39

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

26 AUG 2020 20:22

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:39

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

27 AUG 2020 18:21

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	28 AUG 2020 21:56
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

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 ☐

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 14:29
PC Open Date & Time	22 AUG 2020 14:14
PC Close Date & Time	22 AUG 2020 16:44

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

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 ☐

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 19:57
PC Open Date & Time	22 AUG 2020 17:39
PC Close Date & Time	23 AUG 2020 11:59

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:39

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:39

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 20:49
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:39

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 ☒

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:39

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 19:14
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:39

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)

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:39

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 19:09
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:39

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)

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:39

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 20:22
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:39

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 18:21
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:39

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 21:57
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3402430

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402430

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402430

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402430

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402430

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402430

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402430

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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	VISIT2

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

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)	21 SEP 2020
Time of assessment (00:00-23:59)	15:15 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 15:15
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
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 <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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	

US3402430

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3402430

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

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 HYPERTENSION
Participant, Protocol Deviation, or Other, specify

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3402430

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

15:42 (24 HR)

Collection date and time (derived)

21 SEP 2020 15:42

US3402430

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:45	21 SEP 2020 15:45
Nasopharyngeal Swab 2	No		

US3402430

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402430

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402430

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402430

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402430

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402430

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402430

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402430

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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	VISIT3

US3402430

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 14:55
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402430

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

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.

US3402430

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

15:00 (24 HR)

Collection date and time (derived)

23 OCT 2020 15:00

US3402430

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 18:28:35

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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	25 OCT 2020 20:17:25
Patient Cloud Open Date & Time	22 OCT 2020 00:01
Patient Cloud Close Date & Time	26 OCT 2020 23:59

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

30 OCT 2020 06:59:32

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 06:10:03

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT	DAY 92
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 NOV 2020 17:19:25
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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	25 NOV 2020 12:27:12
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

30 NOV 2020 20:26:16

Patient Cloud Open Date & Time

30 NOV 2020 00:01

Patient Cloud Close Date & Time

04 DEC 2020 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 15:54:56
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 17:53:40
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 DEC 2020 05:19:51
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 19:12:50

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 JAN 2021 16:28:27

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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	11 JAN 2021 18:35:46
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

20 JAN 2021 13:26:16

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

26 JAN 2021 12:21:44

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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	01 FEB 2021 16:14:21
Patient Cloud Open Date & Time	01 FEB 2021 00:01
Patient Cloud Close Date & Time	05 FEB 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

08 FEB 2021 06:02:32

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

17 FEB 2021 10:55:48

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

22 FEB 2021 18:07:36

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 06:53:07

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 14:34:07

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

16 MAR 2021 16:33:02

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

22 MAR 2021 18:50:33

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

29 MAR 2021 17:58:59

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

06 APR 2021 07:08:23

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 APR 2021 12:34:09
Patient Cloud Open Date & Time	12 APR 2021 00:01
Patient Cloud Close Date & Time	16 APR 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 APR 2021 22:51:53

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 18:18:28

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 21:53:11

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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="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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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="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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

12 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	30 JUL 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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="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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 OCT 2021 00:01
Patient Cloud Close Date & Time	22 OCT 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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="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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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="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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

13 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

Patient Cloud Open Date & Time	20 DEC 2021 00:01
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Patient Cloud Close Date & Time	24 DEC 2021 23:59
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US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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 ☐

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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 ☐

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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 ☐

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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 ☐

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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 ☐

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 635

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

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

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

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

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

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

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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="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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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="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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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="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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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 <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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2022 00:01
Patient Cloud Close Date & Time	14 OCT 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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

[Patient Cloud Open Date & Time](#)

17 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	24 OCT 2022 00:01
Patient Cloud Close Date & Time	28 OCT 2022 23:59

US3402430

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:38:39

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		27 FEB 2021 17:15:36

US3402430

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:34:25

Generated On: 11 Aug 2021 22:38:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402430

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:34:25

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402430

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402430

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402430

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402430

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402430

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402430

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402430

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

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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US3402430

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

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) _____

US3402430

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

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.

US3402430

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 MAR 2021

Collection time (00:00-23:59)

13:16 (24 HR)

Collection date and time (derived)

23 MAR 2021 13:16

US3402430

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402430

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402430

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402430

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

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

US3402430

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402430

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:38:39

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"/>

US3402430

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:38:39

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3402430

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

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

Visit date (dd MMM yyyy)	28 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3402430

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Date of updated informed consent (<i>dd MMM yyyy</i>)	06 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>)	28 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

US3402430

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

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

US3402430

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JAN 2021
Time of assessment (00:00-23:59)	08:19 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 08:19
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3402430

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JAN 2021
Time of assessment (00:00-23:59)	09:15 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 09:15
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3402430

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

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JAN 2021

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

US3402430

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

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

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) 28 JAN 2021

What was the treatment time? (00:00-23:59) 08:41 (24 HR)

Treatment Date and Time (derived) 28 JAN 2021 08:41

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

US3402430

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 JAN 2021

Collection time (00:00-23:59)

08:14 (24 HR)

Collection date and time (derived)

28 JAN 2021 08:14

US3402430

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00 - 23:59)	08:10
Collection Date and Time (derived)	28 JAN 2021 08:10

US3402430

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

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402430

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402430

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

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

US3402430

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3402430

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

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)	24 FEB 2021
Time of assessment (00:00-23:59)	08:34 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 08:34
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3402430

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

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)	24 FEB 2021
Time of assessment (00:00-23:59)	09:21 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 09:21
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3402430

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3402430

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

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

What was the treatment time? (00:00-23:59) 08:50 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 08:50

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

US3402430

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402430

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402430

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402430

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

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

US3402430

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

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) _____

US3402430

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

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.

US3402430

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 MAR 2021

Collection time (00:00-23:59)

13:16 (24 HR)

Collection date and time (derived)

23 MAR 2021 13:16

US3402430

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 14:52:26

Generated On: 11 Aug 2021 22:38:39

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3402430

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Mar 2021 14:52:26

Generated On: 11 Aug 2021 22:38:39

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

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Mar 2021 14:52:26

Generated On: 11 Aug 2021 22:38:39

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related <input 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 type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input checked="" type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input type="radio"/>

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input checked="" type="radio"/>
	Unknown <input type="radio"/>

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

Narrative	SUBJECT DID NOT RECEIVE 2ND VACCINATION DUE TO HYPERTENSION AE. SUBJECT WILL REMAIN IN STUDY FOR SAFETY INFORMATION.
-----------	--

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

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

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 23:44:48

Generated On: 11 Aug 2021 22:38:39

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

Yes ☒

No ☐

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

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:44:48

Generated On: 11 Aug 2021 22:38:39

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:44:48

Generated On: 11 Aug 2021 22:38:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:44:48

Generated On: 11 Aug 2021 22:38:39

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:44:48

Generated On: 11 Aug 2021 22:38:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402430

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 23:44:48

Generated On: 11 Aug 2021 22:38:39

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3402430

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 26 Apr 2021 23:57:21

Generated On: 11 Aug 2021 22:38:39

Date of dosing discontinuation (dd MMM yyyy)	21 SEP 2020
--	-------------

Primary reason for dosing discontinuation	AE (specify) <input checked="" type="radio"/>
	SAE (specify) <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-up <input type="radio"/>
	Physician decision (specify) <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol deviation (specify) <input type="radio"/>
	Study Terminated By Sponsor <input type="radio"/>
	Withdrawal of consent by participant (specify) <input type="radio"/>
	Due to SARS-COV-2 <input type="radio"/>
	Other <input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	AE #1
---	-------

US3402430

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:38:39

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3402430 (Prod: Meridian Clinical Research, LLC)

US3402430

Form: Participant Creation

Generated On: 11 Aug 2021 22:38:39

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'US3402430'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 17:39:10

US3402430

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	22 Aug 2020 18:04:14

US3402430

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '22 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 17:39:11

US3402430

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[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 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4)	22 Aug 2020 18:04:14

US3402430

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered 'SCRN'	System	22 Aug 2020 18:04:14

US3402430

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:39

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered (b) (6) 1962'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 17:39:12

US3402430

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:39

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '57'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:38:17

US3402430

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:39

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered 'YEARS'	System	22 Aug 2020 19:38:17

US3402430

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered '57'	System	22 Aug 2020 18:04:37

US3402430

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:39

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:38:17

US3402430

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:39

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:38:17

US3402430

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:39

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:38:17

US3402430

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:39

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:38:17

US3402430

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:39

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:38:17

US3402430

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:38:17

US3402430

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:38:17

US3402430

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:38:17

US3402430

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:39

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:38:17

US3402430

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:39

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:38:17

US3402430

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:39

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:38:17

US3402430

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:39

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '22 Aug 2020'	(b) (4) Jennifer Molstead (b) (4)	22 Aug 2020 18:04:37
	(b) (4)	

US3402430

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered 'Aug 2020'	System	22 Aug 2020 18:04:37

US3402430

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered '2020'	System	22 Aug 2020 18:04:37

US3402430

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:39

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'Amendment 2 (2)'	(b) (4) Jennifer Molstead (b) (4)	22 Aug 2020 18:04:37

US3402430

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'Yes (Y)'	(b) (4)	
	Jennifer Molstead (b) (4)	22 Aug 2020 18:04:37
	(b) (4)	

US3402430

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered empty.	Jennifer Molstead (b) (4)	22 Aug 2020 18:04:37

US3402430

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	22 Aug 2020 18:04:37
	(b) (4)	

US3402430

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'No (N)'	(b) (4)	
	Jennifer Molstead (b) (4)	22 Aug 2020 18:04:37
	(b) (4)	

US3402430

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 17:39:11

US3402430

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered 'I'	System	22 Aug 2020 18:04:44

US3402430

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	22 Aug 2020 18:04:44

US3402430

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:38:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:39:15

US3402430

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User closed query ""	(b) (4)	06 Oct 2020 18:00:08
Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable." ' (Site from DM).	(b) (4), (b) (6)	
Query ""	Tammy Kohn (b) (4)	21 Sep 2020 14:50:28
Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable." ' answered with 'degeneration of joint cartilag' (Site from DM).	(b) (4)	
User opened query ""	(b) (4), (b) (6)	21 Sep 2020 05:56:09
Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable." ' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 19:41:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	
Data point term sent to Coder	System	22 Aug 2020 19:40:32
User entered 'OSTEOARTHRITIS'	(b) (4), (b) (6)	22 Aug 2020 19:40:04

US3402430

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'UN UNK 2013'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:40:04

US3402430

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:40:04

US3402430

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:40:04

US3402430

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:40:04

US3402430

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:40:04

US3402430

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered 'Jan 2013'	System	22 Aug 2020 19:40:04

US3402430

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered '2013'	System	22 Aug 2020 19:40:04

US3402430

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered empty.	System	22 Aug 2020 19:40:04

US3402430

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered empty.	System	22 Aug 2020 19:40:04

US3402430

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User closed query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 18:00:27
Query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify. ' answered with 'decline in reproductive hormones ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	21 Sep 2020 14:51:22
User opened query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 05:57:16
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 19:42:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 19:42:18
Data point term sent to Coder	System	22 Aug 2020 19:41:34
User entered 'POSTMENOPAUSAL'	(b) (4), (b) (6)	22 Aug 2020 19:40:42

US3402430

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'UN Jan 2012'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:40:42

US3402430

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:40:42

US3402430

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:40:42

US3402430

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:40:42

US3402430

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:40:42

US3402430

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered 'Jan 2012'	System	22 Aug 2020 19:40:42

US3402430

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered '2012'	System	22 Aug 2020 19:40:42

US3402430

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered empty.	System	22 Aug 2020 19:40:42

US3402430

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered empty.	System	22 Aug 2020 19:40:42

US3402430

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Aug 2020 19:42:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 19:42:18
Data point term sent to Coder	System	22 Aug 2020 19:41:35
User entered 'TOTAL HYSTERECTOMY'	(b) (4), (b) (6)	22 Aug 2020 19:41:23

US3402430

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'UN Jan 2012'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:41:23

US3402430

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:41:23

US3402430

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:41:23

US3402430

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'UN Jan 2012'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:41:23

US3402430

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:41:23

US3402430

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered 'Jan 2012'	System	22 Aug 2020 19:41:23

US3402430

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered '2012'	System	22 Aug 2020 19:41:23

US3402430

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered 'Jan 2012'	System	22 Aug 2020 19:41:23

US3402430

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered '2012'	System	22 Aug 2020 19:41:23

US3402430

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Aug 2020 05:04:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 05:04:32
Data point term sent to Coder	System	22 Aug 2020 19:42:35
User entered 'GASTROESAPHEGEAL REFLUX DISEASE'	(b) (4), (b) (6)	22 Aug 2020 19:42:13

US3402430

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:42:13

US3402430

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:42:13

US3402430

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:42:13

US3402430

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:42:13

US3402430

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:42:13

US3402430

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered 'Jan 2010'	System	22 Aug 2020 19:42:13

US3402430

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered '2010'	System	22 Aug 2020 19:42:13

US3402430

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered empty.	System	22 Aug 2020 19:42:13

US3402430

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered empty.	System	22 Aug 2020 19:42:13

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:43:46

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '22 Aug 2020'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:43:46

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '13:26'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:43:46

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered '22 Aug 2020 13:26'	System	22 Aug 2020 19:43:46

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '162.3' cm	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:43:46
DataPoint set to visible.	System	22 Aug 2020 18:04:44

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '74.4' kg	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:43:46
DataPoint set to visible.	System	22 Aug 2020 18:04:44

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
Amendment Manager: User entered '28.24463'	System	17 Sep 2020 00:20:08
User entered '28.2'	System	22 Aug 2020 19:43:46
DataPoint set to visible.	System	22 Aug 2020 18:04:44

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered 'kg/m2'	System	22 Aug 2020 19:43:46
DataPoint set to visible.	System	22 Aug 2020 18:04:44

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 20:22:53
User entered '98.2' F	(b) (4), (b) (6)	22 Aug 2020 19:43:46

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered empty; reason for change Data Entry Error	(b) (4)	20 Dec 2020 20:22:53
User entered 'Oral (Oral)'	Tammy Kohn (b) (4)	22 Aug 2020 19:43:46
	(b) (4)	
	(b) (4), (b) (6)	

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:43:46

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 20:22:53
User entered '64'	(b) (4), (b) (6)	22 Aug 2020 19:43:46

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered 'bpm'	System	22 Aug 2020 19:43:46

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 20:22:53
User entered '12'	(b) (4), (b) (6)	22 Aug 2020 19:43:46

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered 'breaths/min'	System	22 Aug 2020 19:43:46

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 20:22:53
User entered '119'	(b) (4), (b) (6)	22 Aug 2020 19:43:46

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered 'mmHg'	System	22 Aug 2020 19:43:46

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 20:22:53
User entered '72'	(b) (4)	22 Aug 2020 19:43:46
	(b) (4), (b) (6)	

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User entered 'mmHg'	System	22 Aug 2020 19:43:46

US3402430

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05

US3402430

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:44:11

US3402430

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '22 Aug 2020'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:44:11

US3402430

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:38:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '22 Aug 2020'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:45:33

US3402430

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:45:33

US3402430

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:38:39

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 11:14:56
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' answered with 'PATIENT HAD CANCEROUS CYSTS IN OVARIES ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 11:16:45
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 04:55:05
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	22 Aug 2020 19:45:48
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	22 Aug 2020 19:45:33
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4), (b) (6)	22 Aug 2020 19:45:33

US3402430

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:45:33

US3402430

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'UN Jan 2012'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:45:33

US3402430

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:38:39

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:45:33

US3402430

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:45:48
User entered 'UN Jan 2012'	(b) (4), (b) (6)	22 Aug 2020 19:45:33

US3402430

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:38:39

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:45:33

US3402430

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

US3402430

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

US3402430

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

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)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

US3402430

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

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)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

US3402430

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

US3402430

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

[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)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

US3402430

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

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)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

US3402430

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

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)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

US3402430

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

[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)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

US3402430

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

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)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

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)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

US3402430

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

US3402430

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

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)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

US3402430

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

[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)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

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)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

US3402430

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

US3402430

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:02:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:45:54
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:27

US3402430

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:47

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '22 Aug 2020'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:47

US3402430

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:46:47

US3402430

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'VISIT1'	System	22 Aug 2020 19:46:47

US3402430

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '22 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 17:39:13

US3402430

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '107416'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 17:39:13

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 17:39:13

US3402430

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:47:04

US3402430

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:47:04

US3402430

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:47:04

US3402430

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:39

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:47:04

US3402430

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:39

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:47:04

US3402430

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:39

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:16:57
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	03 Nov 2020 15:26:22
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	03 Nov 2020 15:26:17
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 12:22:34
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:39:18
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:20:32

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 20:22:33
User entered '162.3' cm	(b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 20:22:33
User entered '74.4' kg	(b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 20:22:33
User entered '162.3' cm	(b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 20:22:33
User entered '74.4' kg	(b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '22 Aug 2020'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '13:26'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered '22 Aug 2020 13:26'	System	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '64'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'bpm'	System	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '12'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'breaths/min'	System	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '119'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'mmHg'	System	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '72'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'mmHg'	System	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 20:22:33
User entered '162.3' cm	(b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 20:22:33
User entered '74.4' kg	(b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '22 Aug 2020'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '14:27'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered '22 Aug 2020 14:27'	System	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '64'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'bpm'	System	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '14'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'breaths/min'	System	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '134'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'mmHg'	System	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '86'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'mmHg'	System	22 Aug 2020 19:49:56

US3402430

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:50:20

US3402430

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '22 Aug 2020'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:50:20

US3402430

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	22 Aug 2020 18:05:40

US3402430

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	Jennifer Molstead (b) (4)	22 Aug 2020 18:05:40

US3402430

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	Jennifer Molstead (b) (4)	22 Aug 2020 18:05:40

US3402430

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'MRNA-1273 OR PLACEBO'	System	22 Aug 2020 18:05:40

US3402430

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '22 Aug 2020'	Jennifer Molstead (b) (4)	22 Aug 2020 18:05:40

US3402430

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '13:54'	Jennifer Molstead (b) (4)	22 Aug 2020 18:05:40

US3402430

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered '22 Aug 2020 13:54'	System	22 Aug 2020 18:05:40

US3402430

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4)	22 Aug 2020 18:05:40

US3402430

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'ONCE'	System	22 Aug 2020 18:05:40

US3402430

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'INTRAMUSCULAR'	System	22 Aug 2020 18:05:40

US3402430

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:51:02

US3402430

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '22 Aug 2020'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:51:02

US3402430

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '13:42'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:51:02

US3402430

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered '22 Aug 2020 13:42'	System	22 Aug 2020 19:51:02

US3402430

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:38:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '22 Aug 2020'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:51:30

US3402430

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Aug 2020 19:51:30

US3402430

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:51:30

US3402430

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '13:39'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:51:30

US3402430

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered '22 Aug 2020 13:39'	System	22 Aug 2020 19:51:30

US3402430

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Aug 2020 19:51:30

US3402430

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:51:30

US3402430

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:51:30

US3402430

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered empty.	System	22 Aug 2020 19:51:30

US3402430

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Aug 2020 19:51:50
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 19:51:43

US3402430

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered '1'	System	22 Aug 2020 19:51:50
User entered empty.	System	22 Aug 2020 19:51:43

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T14:28:29', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'bb1df95a-28b2-4ff9-a987-a643f76c5dd5'	System	22 Aug 2020 18:28:54
User entered 'Yes (Y)'	System	22 Aug 2020 18:28:54

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T14:28:35', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'bb1df95a-28b2-4ff9-a987-a643f76c5dd5'	System	22 Aug 2020 18:28:54
User entered '98.0'	System	22 Aug 2020 18:28:54

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T14:28:43', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'bb1df95a-28b2-4ff9-a987-a643f76c5dd5'	System	22 Aug 2020 18:28:54
User entered 'No (N)'	System	22 Aug 2020 18:28:54

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T14:28:51', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'bb1df95a-28b2-4ff9-a987-a643f76c5dd5'	System	22 Aug 2020 18:28:54
User entered '22 Aug 2020 14:28'	System	22 Aug 2020 18:28:54

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '22 Aug 2020 14:14'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '22 Aug 2020 16:44'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T19:56:39', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '7b77113d-8d13-47a3-9cac-1f71eff45cbd'	System	22 Aug 2020 23:57:02
User entered 'Yes (Y)'	System	22 Aug 2020 23:57:02

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T19:56:44', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '7b77113d-8d13-47a3-9cac-1f71eff45cbd'	System	22 Aug 2020 23:57:02
User entered '97.6'	System	22 Aug 2020 23:57:02

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T19:56:50', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '7b77113d-8d13-47a3-9cac-1f71eff45cbd'	System	22 Aug 2020 23:57:02
User entered 'No (N)'	System	22 Aug 2020 23:57:02

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T19:56:54', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '7b77113d-8d13-47a3-9cac-1f71eff45cbd'	System	22 Aug 2020 23:57:02
User entered '22 Aug 2020 19:56'	System	22 Aug 2020 23:57:02

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '22 Aug 2020 17:39'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 2'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-23T20:48:06', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '5d2d7d82-a890-406e-827b-caab853b59a0'	System	24 Aug 2020 00:48:27
User entered 'Yes (Y)'	System	24 Aug 2020 00:48:27

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-23T20:48:11', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '5d2d7d82-a890-406e-827b-caab853b59a0'	System	24 Aug 2020 00:48:27
User entered '96.8'	System	24 Aug 2020 00:48:27

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-23T20:48:16', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '5d2d7d82-a890-406e-827b-caab853b59a0'	System	24 Aug 2020 00:48:27
User entered 'No (N)'	System	24 Aug 2020 00:48:27

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-23T20:48:24', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '5d2d7d82-a890-406e-827b-caab853b59a0'	System	24 Aug 2020 00:48:27
User entered '23 Aug 2020 20:48'	System	24 Aug 2020 00:48:27

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 3'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-24T19:13:33', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'b1cc7784-6e4b-47f3-b034-ce24806f4aee'	System	24 Aug 2020 23:13:55
User entered 'Yes (Y)'	System	24 Aug 2020 23:13:55

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-24T19:13:37', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'b1cc7784-6e4b-47f3-b034-ce24806f4aee'	System	24 Aug 2020 23:13:55
User entered '97.2'	System	24 Aug 2020 23:13:55

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-24T19:13:42', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'b1cc7784-6e4b-47f3-b034-ce24806f4aee'	System	24 Aug 2020 23:13:55
User entered 'No (N)'	System	24 Aug 2020 23:13:55

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-24T19:13:52', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'b1cc7784-6e4b-47f3-b034-ce24806f4aee'	System	24 Aug 2020 23:13:55
User entered '24 Aug 2020 19:13'	System	24 Aug 2020 23:13:55

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 4'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-25T19:08:01', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'a072af80-62cb-4a70-98d4-a519e52b317b'	System	25 Aug 2020 23:08:48
User entered 'Yes (Y)'	System	25 Aug 2020 23:08:48

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-25T19:08:35', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'a072af80-62cb-4a70-98d4-a519e52b317b'	System	25 Aug 2020 23:08:48
User entered '97.2'	System	25 Aug 2020 23:08:48

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-25T19:08:40', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'a072af80-62cb-4a70-98d4-a519e52b317b'	System	25 Aug 2020 23:08:48
User entered 'No (N)'	System	25 Aug 2020 23:08:48

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-25T19:08:44', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'a072af80-62cb-4a70-98d4-a519e52b317b'	System	25 Aug 2020 23:08:48
User entered '25 Aug 2020 19:08'	System	25 Aug 2020 23:08:48

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 5'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-26T20:21:51', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '69be3c8a-c75c-4d38-a06e-24b073c3fdb1'	System	27 Aug 2020 00:22:11
User entered 'Yes (Y)'	System	27 Aug 2020 00:22:11

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-26T20:21:57', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '69be3c8a-c75c-4d38-a06e-24b073c3fdb1'	System	27 Aug 2020 00:22:11
User entered '96.8'	System	27 Aug 2020 00:22:11

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-26T20:22:05', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '69be3c8a-c75c-4d38-a06e-24b073c3fdb1'	System	27 Aug 2020 00:22:11
User entered 'No (N)'	System	27 Aug 2020 00:22:11

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-26T20:22:09', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '69be3c8a-c75c-4d38-a06e-24b073c3fdb1'	System	27 Aug 2020 00:22:11
User entered '26 Aug 2020 20:22'	System	27 Aug 2020 00:22:11

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 6'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-27T18:21:03', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '8228ab02-146d-44df-9538-d9f0ede813ed'	System	27 Aug 2020 22:21:18
User entered 'Yes (Y)'	System	27 Aug 2020 22:21:18

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-27T18:21:07', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '8228ab02-146d-44df-9538-d9f0ede813ed' User entered '97.7'	System	27 Aug 2020 22:21:18
	System	27 Aug 2020 22:21:18

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-27T18:21:11', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '8228ab02-146d-44df-9538-d9f0ede813ed'	System	27 Aug 2020 22:21:18
User entered 'No (N)'	System	27 Aug 2020 22:21:18

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-27T18:21:14', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '8228ab02-146d-44df-9538-d9f0ede813ed'	System	27 Aug 2020 22:21:18
User entered '27 Aug 2020 18:21'	System	27 Aug 2020 22:21:18

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 7'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-28T21:55:58', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '27633bfd-9532-4df3-820e-acfd9dfdba2e'	System	29 Aug 2020 01:56:30
User entered 'Yes (Y)'	System	29 Aug 2020 01:56:30

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-28T21:56:20', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '27633bfd-9532-4df3-820e-acfd9dfdba2e'	System	29 Aug 2020 01:56:30
User entered '96.3'	System	29 Aug 2020 01:56:30

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-28T21:56:23', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '27633bfd-9532-4df3-820e-acfd9dfdba2e'	System	29 Aug 2020 01:56:30
User entered 'No (N)'	System	29 Aug 2020 01:56:30

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-28T21:56:27', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '27633bfd-9532-4df3-820e-acfd9dfdba2e'	System	29 Aug 2020 01:56:30
User entered '28 Aug 2020 21:56'	System	29 Aug 2020 01:56:30

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T14:29:57', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'd2b050bb-50de-4b2e-ad37-4876f50516d7'	System	22 Aug 2020 18:30:17
User entered 'None (1)'	System	22 Aug 2020 18:30:17

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T14:30:05', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'd2b050bb-50de-4b2e-ad37-4876f50516d7'	System	22 Aug 2020 18:30:17
User entered 'No (N)'	System	22 Aug 2020 18:30:17

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T14:30:07', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'd2b050bb-50de-4b2e-ad37-4876f50516d7'	System	22 Aug 2020 18:30:17
User entered 'No (N)'	System	22 Aug 2020 18:30:17

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T14:30:11', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'd2b050bb-50de-4b2e-ad37-4876f50516d7'	System	22 Aug 2020 18:30:17
User entered 'None (1)'	System	22 Aug 2020 18:30:17

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T14:30:15', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'd2b050bb-50de-4b2e-ad37-4876f50516d7'	System	22 Aug 2020 18:30:17
User entered '22 Aug 2020 14:30'	System	22 Aug 2020 18:30:17

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '22 Aug 2020 14:14'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '22 Aug 2020 16:44'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T19:57:02', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '219729d9-ba28-4161-9d75-5ec96b9abcdf'	System	22 Aug 2020 23:57:19
User entered 'None (1)'	System	22 Aug 2020 23:57:19

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T19:57:06', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '219729d9-ba28-4161-9d75-5ec96b9abcdf'	System	22 Aug 2020 23:57:19
User entered 'No (N)'	System	22 Aug 2020 23:57:19

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T19:57:09', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '219729d9-ba28-4161-9d75-5ec96b9abcdf'	System	22 Aug 2020 23:57:19
User entered 'No (N)'	System	22 Aug 2020 23:57:19

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T19:57:12', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '219729d9-ba28-4161-9d75-5ec96b9abcdf'	System	22 Aug 2020 23:57:19
User entered 'None (1)'	System	22 Aug 2020 23:57:19

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T19:57:16', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '219729d9-ba28-4161-9d75-5ec96b9abcdf'	System	22 Aug 2020 23:57:19
User entered '22 Aug 2020 19:57'	System	22 Aug 2020 23:57:19

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '22 Aug 2020 17:39'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 2'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-23T20:48:30', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6066278b-ab3e-4afb-89e6-d9bc4d15ea93'	System	24 Aug 2020 00:48:47
User entered 'None (1)'	System	24 Aug 2020 00:48:47

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-23T20:48:33', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6066278b-ab3e-4afb-89e6-d9bc4d15ea93'	System	24 Aug 2020 00:48:47
User entered 'No (N)'	System	24 Aug 2020 00:48:47

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-23T20:48:36', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6066278b-ab3e-4afb-89e6-d9bc4d15ea93'	System	24 Aug 2020 00:48:47
User entered 'No (N)'	System	24 Aug 2020 00:48:47

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-23T20:48:42', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6066278b-ab3e-4afb-89e6-d9bc4d15ea93'	System	24 Aug 2020 00:48:47
User entered 'None (1)'	System	24 Aug 2020 00:48:47

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-23T20:48:45', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6066278b-ab3e-4afb-89e6-d9bc4d15ea93'	System	24 Aug 2020 00:48:47
User entered '23 Aug 2020 20:48'	System	24 Aug 2020 00:48:47

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 3'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-24T19:13:55', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '902977a1-ee81-4291-853e-ecebf262ea28'	System	24 Aug 2020 23:14:08
User entered 'None (1)'	System	24 Aug 2020 23:14:08

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-24T19:13:58', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '902977a1-ee81-4291-853e-ecebf262ea28'	System	24 Aug 2020 23:14:08
User entered 'No (N)'	System	24 Aug 2020 23:14:08

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-24T19:14:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '902977a1-ee81-4291-853e-ecebf262ea28'	System	24 Aug 2020 23:14:08
User entered 'No (N)'	System	24 Aug 2020 23:14:08

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-24T19:14:03', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '902977a1-ee81-4291-853e-ecebf262ea28'	System	24 Aug 2020 23:14:08
User entered 'None (1)'	System	24 Aug 2020 23:14:08

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-24T19:14:05', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '902977a1-ee81-4291-853e-ecebf262ea28'	System	24 Aug 2020 23:14:08
User entered '24 Aug 2020 19:14'	System	24 Aug 2020 23:14:08

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 4'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-25T19:08:49', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '207e1c6d-a472-4f1d-a8d8-66ac9ab4888d'	System	25 Aug 2020 23:09:04
User entered 'None (1)'	System	25 Aug 2020 23:09:04

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-25T19:08:52', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '207e1c6d-a472-4f1d-a8d8-66ac9ab4888d'	System	25 Aug 2020 23:09:04
User entered 'No (N)'	System	25 Aug 2020 23:09:04

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-25T19:08:54', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '207e1c6d-a472-4f1d-a8d8-66ac9ab4888d'	System	25 Aug 2020 23:09:04
User entered 'No (N)'	System	25 Aug 2020 23:09:04

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-25T19:08:57', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '207e1c6d-a472-4f1d-a8d8-66ac9ab4888d'	System	25 Aug 2020 23:09:04
User entered 'None (1)'	System	25 Aug 2020 23:09:04

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-25T19:09:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '207e1c6d-a472-4f1d-a8d8-66ac9ab4888d'	System	25 Aug 2020 23:09:04
User entered '25 Aug 2020 19:09'	System	25 Aug 2020 23:09:04

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 5'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-26T20:22:13', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '80dade2e-7133-493b-b67d-76df7580dec1'	System	27 Aug 2020 00:22:33
User entered 'None (1)'	System	27 Aug 2020 00:22:33

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-26T20:22:16', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '80dade2e-7133-493b-b67d-76df7580dec1'	System	27 Aug 2020 00:22:33
User entered 'No (N)'	System	27 Aug 2020 00:22:33

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-26T20:22:19', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '80dade2e-7133-493b-b67d-76df7580dec1'	System	27 Aug 2020 00:22:33
User entered 'No (N)'	System	27 Aug 2020 00:22:33

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-26T20:22:21', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '80dade2e-7133-493b-b67d-76df7580dec1'	System	27 Aug 2020 00:22:33
User entered 'None (1)'	System	27 Aug 2020 00:22:33

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-26T20:22:25', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '80dade2e-7133-493b-b67d-76df7580dec1'	System	27 Aug 2020 00:22:33
User entered '26 Aug 2020 20:22'	System	27 Aug 2020 00:22:33

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 6'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-27T18:21:17', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'ded766a4-a268-4965-8807-373e8a237f39'	System	27 Aug 2020 22:21:36
User entered 'None (1)'	System	27 Aug 2020 22:21:36

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-27T18:21:20', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'ded766a4-a268-4965-8807-373e8a237f39'	System	27 Aug 2020 22:21:36
User entered 'No (N)'	System	27 Aug 2020 22:21:36

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-27T18:21:22', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'ded766a4-a268-4965-8807-373e8a237f39'	System	27 Aug 2020 22:21:36
User entered 'No (N)'	System	27 Aug 2020 22:21:36

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-27T18:21:27', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'ded766a4-a268-4965-8807-373e8a237f39'	System	27 Aug 2020 22:21:36
User entered 'None (1)'	System	27 Aug 2020 22:21:36

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-27T18:21:29', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'ded766a4-a268-4965-8807-373e8a237f39'	System	27 Aug 2020 22:21:36
User entered '27 Aug 2020 18:21'	System	27 Aug 2020 22:21:36

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 7'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-28T21:56:31', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '7a59d2bd-4d60-4e5d-af51-a7ed9fb7154f'	System	29 Aug 2020 01:56:46
User entered 'None (1)'	System	29 Aug 2020 01:56:46

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-28T21:56:34', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '7a59d2bd-4d60-4e5d-af51-a7ed9fb7154f'	System	29 Aug 2020 01:56:46
User entered 'No (N)'	System	29 Aug 2020 01:56:46

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-28T21:56:36', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '7a59d2bd-4d60-4e5d-af51-a7ed9fb7154f'	System	29 Aug 2020 01:56:46
User entered 'No (N)'	System	29 Aug 2020 01:56:46

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:39

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-28T21:56:38', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '7a59d2bd-4d60-4e5d-af51-a7ed9fb7154f'	System	29 Aug 2020 01:56:46
User entered 'None (1)'	System	29 Aug 2020 01:56:46

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-28T21:56:42', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '7a59d2bd-4d60-4e5d-af51-a7ed9fb7154f'	System	29 Aug 2020 01:56:46
User entered '28 Aug 2020 21:56'	System	29 Aug 2020 01:56:46

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T14:29:22', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'f9874689-deb4-4bf6-aa17-a18f07f71c9d'	System	22 Aug 2020 18:29:52
User entered 'No interference with activity (1)'	System	22 Aug 2020 18:29:52

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T14:29:25', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'f9874689-deb4-4bf6-aa17-a18f07f71c9d'	System	22 Aug 2020 18:29:52
User entered 'None (0)'	System	22 Aug 2020 18:29:52

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T14:29:28', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'f9874689-deb4-4bf6-aa17-a18f07f71c9d'	System	22 Aug 2020 18:29:52
User entered 'None (0)'	System	22 Aug 2020 18:29:52

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T14:29:30', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'f9874689-deb4-4bf6-aa17-a18f07f71c9d'	System	22 Aug 2020 18:29:52
User entered 'None (0)'	System	22 Aug 2020 18:29:52

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T14:29:32', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'f9874689-deb4-4bf6-aa17-a18f07f71c9d'	System	22 Aug 2020 18:29:52
User entered 'None (0)'	System	22 Aug 2020 18:29:52

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T14:29:34', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'f9874689-deb4-4bf6-aa17-a18f07f71c9d'	System	22 Aug 2020 18:29:52
User entered 'None (0)'	System	22 Aug 2020 18:29:52

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

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)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T14:29:40', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'f9874689-deb4-4bf6-aa17-a18f07f71c9d'	System	22 Aug 2020 18:29:52
User entered 'No (N)'	System	22 Aug 2020 18:29:52

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T14:29:48', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'f9874689-deb4-4bf6-aa17-a18f07f71c9d'	System	22 Aug 2020 18:29:52
User entered '22 Aug 2020 14:29'	System	22 Aug 2020 18:29:52

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '22 Aug 2020 14:14'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '22 Aug 2020 16:44'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T19:57:21', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6baa068b-524e-4d9e-8b7d-23bed980c9ee'	System	22 Aug 2020 23:57:54
User entered 'None (0)'	System	22 Aug 2020 23:57:54

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T19:57:24', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6baa068b-524e-4d9e-8b7d-23bed980c9ee'	System	22 Aug 2020 23:57:54
User entered 'None (0)'	System	22 Aug 2020 23:57:54

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T19:57:27', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6baa068b-524e-4d9e-8b7d-23bed980c9ee'	System	22 Aug 2020 23:57:54
User entered 'None (0)'	System	22 Aug 2020 23:57:54

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T19:57:33', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6baa068b-524e-4d9e-8b7d-23bed980c9ee'	System	22 Aug 2020 23:57:54
User entered 'None (0)'	System	22 Aug 2020 23:57:54

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T19:57:36', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6baa068b-524e-4d9e-8b7d-23bed980c9ee'	System	22 Aug 2020 23:57:54
User entered 'None (0)'	System	22 Aug 2020 23:57:54

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T19:57:38', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6baa068b-524e-4d9e-8b7d-23bed980c9ee'	System	22 Aug 2020 23:57:54
User entered 'None (0)'	System	22 Aug 2020 23:57:54

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

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)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T19:57:44', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6baa068b-524e-4d9e-8b7d-23bed980c9ee'	System	22 Aug 2020 23:57:54
User entered 'No (N)'	System	22 Aug 2020 23:57:54

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-22T19:57:49', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6baa068b-524e-4d9e-8b7d-23bed980c9ee'	System	22 Aug 2020 23:57:54
User entered '22 Aug 2020 19:57'	System	22 Aug 2020 23:57:54

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '22 Aug 2020 17:39'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 2'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-23T20:48:50', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '5e41363d-c0b0-40df-8f7f-0b9618ead3af'	System	24 Aug 2020 00:49:11
User entered 'None (0)'	System	24 Aug 2020 00:49:11

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-23T20:48:52', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '5e41363d-c0b0-40df-8f7f-0b9618ead3af'	System	24 Aug 2020 00:49:11
User entered 'None (0)'	System	24 Aug 2020 00:49:11

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-23T20:48:53', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '5e41363d-c0b0-40df-8f7f-0b9618ead3af'	System	24 Aug 2020 00:49:11
User entered 'None (0)'	System	24 Aug 2020 00:49:11

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-23T20:48:55', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '5e41363d-c0b0-40df-8f7f-0b9618ead3af'	System	24 Aug 2020 00:49:11
User entered 'None (0)'	System	24 Aug 2020 00:49:11

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-23T20:48:57', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '5e41363d-c0b0-40df-8f7f-0b9618ead3af'	System	24 Aug 2020 00:49:11
User entered 'None (0)'	System	24 Aug 2020 00:49:11

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-23T20:48:59', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '5e41363d-c0b0-40df-8f7f-0b9618ead3af'	System	24 Aug 2020 00:49:11
User entered 'None (0)'	System	24 Aug 2020 00:49:11

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:39

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)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-23T20:49:04', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '5e41363d-c0b0-40df-8f7f-0b9618ead3af'	System	24 Aug 2020 00:49:11
User entered 'No (N)'	System	24 Aug 2020 00:49:11

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-23T20:49:09', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '5e41363d-c0b0-40df-8f7f-0b9618ead3af'	System	24 Aug 2020 00:49:11
User entered '23 Aug 2020 20:49'	System	24 Aug 2020 00:49:11

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 3'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-24T19:14:10', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '81f9fed6-2311-418b-9193-26ce18721458'	System	24 Aug 2020 23:14:34
User entered 'None (0)'	System	24 Aug 2020 23:14:34

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-24T19:14:12', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '81f9fed6-2311-418b-9193-26ce18721458'	System	24 Aug 2020 23:14:34
User entered 'None (0)'	System	24 Aug 2020 23:14:34

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-24T19:14:14', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '81f9fed6-2311-418b-9193-26ce18721458'	System	24 Aug 2020 23:14:34
User entered 'None (0)'	System	24 Aug 2020 23:14:34

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-24T19:14:16', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '81f9fed6-2311-418b-9193-26ce18721458'	System	24 Aug 2020 23:14:34
User entered 'None (0)'	System	24 Aug 2020 23:14:34

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-24T19:14:18', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '81f9fed6-2311-418b-9193-26ce18721458'	System	24 Aug 2020 23:14:34
User entered 'None (0)'	System	24 Aug 2020 23:14:34

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-24T19:14:20', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '81f9fed6-2311-418b-9193-26ce18721458'	System	24 Aug 2020 23:14:34
User entered 'None (0)'	System	24 Aug 2020 23:14:34

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:39

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)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-24T19:14:25', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '81f9fed6-2311-418b-9193-26ce18721458'	System	24 Aug 2020 23:14:34
User entered 'No (N)'	System	24 Aug 2020 23:14:34

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-24T19:14:28', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '81f9fed6-2311-418b-9193-26ce18721458'	System	24 Aug 2020 23:14:34
User entered '24 Aug 2020 19:14'	System	24 Aug 2020 23:14:34

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 4'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-25T19:09:07', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '69a3bc21-7f9f-40eb-b273-a468bb971c42'	System	25 Aug 2020 23:09:43
User entered 'None (0)'	System	25 Aug 2020 23:09:43

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-25T19:09:12', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '69a3bc21-7f9f-40eb-b273-a468bb971c42'	System	25 Aug 2020 23:09:43
User entered 'None (0)'	System	25 Aug 2020 23:09:43

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-25T19:09:21', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '69a3bc21-7f9f-40eb-b273-a468bb971c42'	System	25 Aug 2020 23:09:43
User entered 'None (0)'	System	25 Aug 2020 23:09:43

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-25T19:09:27', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '69a3bc21-7f9f-40eb-b273-a468bb971c42'	System	25 Aug 2020 23:09:43
User entered 'None (0)'	System	25 Aug 2020 23:09:43

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-25T19:09:31', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '69a3bc21-7f9f-40eb-b273-a468bb971c42'	System	25 Aug 2020 23:09:43
User entered 'None (0)'	System	25 Aug 2020 23:09:43

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-25T19:09:34', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '69a3bc21-7f9f-40eb-b273-a468bb971c42'	System	25 Aug 2020 23:09:43
User entered 'None (0)'	System	25 Aug 2020 23:09:43

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:39

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)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-25T19:09:37', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '69a3bc21-7f9f-40eb-b273-a468bb971c42'	System	25 Aug 2020 23:09:43
User entered 'No (N)'	System	25 Aug 2020 23:09:43

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-25T19:09:39', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '69a3bc21-7f9f-40eb-b273-a468bb971c42'	System	25 Aug 2020 23:09:43
User entered '25 Aug 2020 19:09'	System	25 Aug 2020 23:09:43

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 5'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-26T20:22:29', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '2434ffe5-fb74-464d-a901-14ea6daa968c'	System	27 Aug 2020 00:22:50
User entered 'None (0)'	System	27 Aug 2020 00:22:50

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-26T20:22:31', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '2434ffe5-fb74-464d-a901-14ea6daa968c'	System	27 Aug 2020 00:22:50
User entered 'None (0)'	System	27 Aug 2020 00:22:50

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-26T20:22:32', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '2434ffe5-fb74-464d-a901-14ea6daa968c'	System	27 Aug 2020 00:22:50
User entered 'None (0)'	System	27 Aug 2020 00:22:50

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-26T20:22:34', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '2434ffe5-fb74-464d-a901-14ea6daa968c'	System	27 Aug 2020 00:22:50
User entered 'None (0)'	System	27 Aug 2020 00:22:50

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-26T20:22:36', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '2434ffe5-fb74-464d-a901-14ea6daa968c'	System	27 Aug 2020 00:22:50
User entered 'None (0)'	System	27 Aug 2020 00:22:50

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-26T20:22:38', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '2434ffe5-fb74-464d-a901-14ea6daa968c'	System	27 Aug 2020 00:22:50
User entered 'None (0)'	System	27 Aug 2020 00:22:50

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:39

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)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-26T20:22:41', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '2434ffe5-fb74-464d-a901-14ea6daa968c'	System	27 Aug 2020 00:22:50
User entered 'No (N)'	System	27 Aug 2020 00:22:50

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-26T20:22:44', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '2434ffe5-fb74-464d-a901-14ea6daa968c'	System	27 Aug 2020 00:22:50
User entered '26 Aug 2020 20:22'	System	27 Aug 2020 00:22:50

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 6'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-27T18:21:33', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'ced4cbb6-745a-4fb9-8e5b-48d3e4c1e486'	System	27 Aug 2020 22:21:51
User entered 'None (0)'	System	27 Aug 2020 22:21:51

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-27T18:21:35', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'ced4cbb6-745a-4fb9-8e5b-48d3e4c1e486'	System	27 Aug 2020 22:21:51
User entered 'None (0)'	System	27 Aug 2020 22:21:51

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-27T18:21:36', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'ced4cbb6-745a-4fb9-8e5b-48d3e4c1e486'	System	27 Aug 2020 22:21:51
User entered 'None (0)'	System	27 Aug 2020 22:21:51

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-27T18:21:38', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'ced4cbb6-745a-4fb9-8e5b-48d3e4c1e486'	System	27 Aug 2020 22:21:51
User entered 'None (0)'	System	27 Aug 2020 22:21:51

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-27T18:21:39', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'ced4cbb6-745a-4fb9-8e5b-48d3e4c1e486'	System	27 Aug 2020 22:21:51
User entered 'None (0)'	System	27 Aug 2020 22:21:51

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-27T18:21:41', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'ced4cbb6-745a-4fb9-8e5b-48d3e4c1e486'	System	27 Aug 2020 22:21:51
User entered 'None (0)'	System	27 Aug 2020 22:21:51

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:39

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)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-27T18:21:43', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'ced4cbb6-745a-4fb9-8e5b-48d3e4c1e486'	System	27 Aug 2020 22:21:51
User entered 'No (N)'	System	27 Aug 2020 22:21:51

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-27T18:21:46', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'ced4cbb6-745a-4fb9-8e5b-48d3e4c1e486'	System	27 Aug 2020 22:21:51
User entered '27 Aug 2020 18:21'	System	27 Aug 2020 22:21:51

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 7'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-28T21:56:46', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'cd6d3efa-eadc-4194-bdf6-dc9d15247f62'	System	29 Aug 2020 01:57:03
User entered 'None (0)'	System	29 Aug 2020 01:57:03

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-28T21:56:47', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'cd6d3efa-eadc-4194-bdf6-dc9d15247f62'	System	29 Aug 2020 01:57:03
User entered 'None (0)'	System	29 Aug 2020 01:57:03

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-28T21:56:49', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'cd6d3efa-eadc-4194-bdf6-dc9d15247f62'	System	29 Aug 2020 01:57:03
User entered 'None (0)'	System	29 Aug 2020 01:57:03

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-28T21:56:51', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'cd6d3efa-eadc-4194-bdf6-dc9d15247f62'	System	29 Aug 2020 01:57:03
User entered 'None (0)'	System	29 Aug 2020 01:57:03

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-28T21:56:53', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'cd6d3efa-eadc-4194-bdf6-dc9d15247f62'	System	29 Aug 2020 01:57:03
User entered 'None (0)'	System	29 Aug 2020 01:57:03

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-28T21:56:55', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'cd6d3efa-eadc-4194-bdf6-dc9d15247f62'	System	29 Aug 2020 01:57:03
User entered 'None (0)'	System	29 Aug 2020 01:57:03

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:39

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)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-28T21:56:58', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'cd6d3efa-eadc-4194-bdf6-dc9d15247f62'	System	29 Aug 2020 01:57:03
User entered 'No (N)'	System	29 Aug 2020 01:57:03

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-08-28T21:57:01', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'cd6d3efa-eadc-4194-bdf6-dc9d15247f62'	System	29 Aug 2020 01:57:03
User entered '28 Aug 2020 21:57'	System	29 Aug 2020 01:57:03

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 18:05:40

US3402430

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	(b) (4)	31 Aug 2020 11:28:00
	Traci Hull (b) (4)	
	(b) (4)	

US3402430

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '29 Aug 2020'	Traci Hull (b) (4)	31 Aug 2020 11:28:00

US3402430

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	31 Aug 2020 11:28:00

US3402430

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	Traci Hull (b) (4)	31 Aug 2020 11:28:00

US3402430

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	31 Aug 2020 11:28:06

US3402430

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'I'	System	31 Aug 2020 11:28:06

US3402430

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	16 Sep 2020 12:18:07

US3402430

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '5 Sep 2020'	Traci Hull (b) (4)	16 Sep 2020 12:18:07

US3402430

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	16 Sep 2020 12:18:07

US3402430

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	Traci Hull (b) (4)	16 Sep 2020 12:18:07

US3402430

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	Traci Hull (b) (4)	16 Sep 2020 12:18:11

US3402430

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'I'	System	16 Sep 2020 12:18:11

US3402430

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	Traci Hull (b) (4)	16 Sep 2020 12:18:26

US3402430

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '12 Sep 2020'	Traci Hull (b) (4)	16 Sep 2020 12:18:26

US3402430

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	16 Sep 2020 12:18:26

US3402430

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	Traci Hull (b) (4)	16 Sep 2020 12:18:26

US3402430

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	Traci Hull (b) (4)	16 Sep 2020 12:18:30

US3402430

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'I'	System	16 Sep 2020 12:18:30

US3402430

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	21 Sep 2020 20:06:29

US3402430

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '21 Sep 2020'	(b) (4)	
	Traci Hull (b) (4)	21 Sep 2020 20:06:29
	(b) (4)	

US3402430

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	21 Sep 2020 20:06:29

US3402430

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'VISIT2'	System	21 Sep 2020 20:06:29

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '21 Sep 2020'	Traci Hull (b) (4)	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '15:15'	(b) (4) Traci Hull (b) (4) (b) (4)	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered '21 Sep 2020 15:15'	System	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '36.4' C	Traci Hull (b) (4)	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	21 Sep 2020 20:07:59
	(b) (4)	

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '84'	(b) (4) Traci Hull (b) (4)	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'bpm'	System	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '14'	(b) (4) Traci Hull (b) (4)	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'breaths/min'	System	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '150'	(b) (4) Traci Hull (b) (4)	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'mmHg'	System	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '86'	Traci Hull (b) (4)	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'mmHg'	System	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	21 Sep 2020 20:07:59

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'No (N)'	(b) (4)	
	Traci Hull (b) (4)	21 Sep 2020 20:07:59
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	(b) (4) Traci Hull (b) (4)	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	(b) (4) Traci Hull (b) (4)	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered empty.	System	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	21 Sep 2020 20:07:59
	(b) (4)	

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	21 Sep 2020 20:07:59
	(b) (4)	

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	21 Sep 2020 20:07:59
	(b) (4)	

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	(b) (4) Traci Hull (b) (4)	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered empty.	System	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	(b) (4) Traci Hull (b) (4)	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered empty.	System	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	21 Sep 2020 20:07:59
	(b) (4)	

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered empty.	System	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	21 Sep 2020 20:07:59
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered empty.	System	21 Sep 2020 20:07:59

US3402430

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	21 Sep 2020 20:08:06

US3402430

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '21 Sep 2020'	(b) (4)	
	Traci Hull (b) (4)	21 Sep 2020 20:08:06
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'No (N)'	Traci Hull (b) (4)	21 Sep 2020 20:08:54

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	Traci Hull (b) (4)	21 Sep 2020 20:08:54

US3402430

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'HYPERTENSION'	Traci Hull (b) (4)	21 Sep 2020 20:08:54

US3402430

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered empty.	System	21 Sep 2020 20:08:54

US3402430

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	Traci Hull (b) (4)	21 Sep 2020 20:08:54

US3402430

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	(b) (4) Traci Hull (b) (4)	21 Sep 2020 20:08:54

US3402430

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered empty.	System	21 Sep 2020 20:08:54

US3402430

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	(b) (4) Traci Hull (b) (4)	21 Sep 2020 20:08:54

US3402430

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered empty.	System	21 Sep 2020 20:08:54

US3402430

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered empty.	System	21 Sep 2020 20:08:54

US3402430

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	Traci Hull (b) (4)	21 Sep 2020 20:09:14

US3402430

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '21 Sep 2020'	(b) (4) Traci Hull (b) (4)	21 Sep 2020 20:09:14

US3402430

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '15:42'	(b) (4)	
	Traci Hull (b) (4)	21 Sep 2020 20:09:14
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered '21 Sep 2020 15:42'	System	21 Sep 2020 20:09:14

US3402430

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:38:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '21 Sep 2020'	Traci Hull (b) (4)	21 Sep 2020 20:09:29

US3402430

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	21 Sep 2020 20:09:29

US3402430

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	21 Sep 2020 20:09:29

US3402430

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '15:45'	Traci Hull (b) (4)	21 Sep 2020 20:09:29

US3402430

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered '21 Sep 2020 15:45'	System	21 Sep 2020 20:09:29

US3402430

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	21 Sep 2020 20:09:29

US3402430

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	21 Sep 2020 20:09:29

US3402430

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	Traci Hull (b) (4)	21 Sep 2020 20:09:29

US3402430

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered empty.	System	21 Sep 2020 20:09:29

US3402430

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	Traci Hull (b) (4)	21 Sep 2020 20:09:34

US3402430

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered '1'	System	21 Sep 2020 20:09:34

US3402430

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	Traci Hull (b) (4)	29 Sep 2020 19:53:17

US3402430

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '28 Sep 2020'	Traci Hull (b) (4)	29 Sep 2020 19:53:17

US3402430

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	29 Sep 2020 19:53:17

US3402430

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	29 Sep 2020 19:53:17
	(b) (4)	

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Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	Traci Hull (b) (4)	29 Sep 2020 19:53:21

US3402430

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'I'	System	29 Sep 2020 19:53:21

US3402430

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	Traci Hull (b) (4)	09 Oct 2020 15:17:47

US3402430

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '7 Oct 2020'	(b) (4) Traci Hull (b) (4)	09 Oct 2020 15:17:47

US3402430

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	09 Oct 2020 15:17:47

US3402430

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	Traci Hull (b) (4)	09 Oct 2020 15:17:47

US3402430

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	Traci Hull (b) (4)	09 Oct 2020 15:17:51

US3402430

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'I'	System	09 Oct 2020 15:17:51

US3402430

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	12 Oct 2020 20:08:38

US3402430

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '12 Oct 2020'	Traci Hull (b) (4)	12 Oct 2020 20:08:38

US3402430

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	12 Oct 2020 20:08:38

US3402430

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	Traci Hull (b) (4)	12 Oct 2020 20:08:38

US3402430

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	Traci Hull (b) (4)	12 Oct 2020 20:08:28

US3402430

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'I'	System	12 Oct 2020 20:08:28

US3402430

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	23 Oct 2020 20:12:29

US3402430

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '23 Oct 2020'	(b) (4) Tammy Kohn (b) (4)	23 Oct 2020 20:12:29

US3402430

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Clinic (Clinic)'	Tammy Kohn (b) (4)	23 Oct 2020 20:12:29

US3402430

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'VISIT3'	System	23 Oct 2020 20:12:29

US3402430

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	23 Oct 2020 20:13:13

US3402430

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '23 Oct 2020'	Tammy Kohn (b) (4)	23 Oct 2020 20:13:13

US3402430

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '14:55'	(b) (4) Tammy Kohn (b) (4)	23 Oct 2020 20:13:13

US3402430

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered '23 Oct 2020 14:55'	System	23 Oct 2020 20:13:13

US3402430

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '36.9' C	Tammy Kohn (b) (4)	23 Oct 2020 20:13:13

US3402430

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Oral (Oral)'	(b) (4) Tammy Kohn (b) (4)	23 Oct 2020 20:13:13

US3402430

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	(b) (4) Tammy Kohn (b) (4)	23 Oct 2020 20:13:13

US3402430

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '70'	Tammy Kohn (b) (4)	23 Oct 2020 20:13:13

US3402430

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'bpm'	System	23 Oct 2020 20:13:13

US3402430

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '14'	Tammy Kohn (b) (4)	23 Oct 2020 20:13:13

US3402430

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'breaths/min'	System	23 Oct 2020 20:13:13

US3402430

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '126'	Tammy Kohn (b) (4)	23 Oct 2020 20:13:13

US3402430

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'mmHg'	System	23 Oct 2020 20:13:13

US3402430

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '67'	Tammy Kohn (b) (4)	23 Oct 2020 20:13:13

US3402430

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'mmHg'	System	23 Oct 2020 20:13:13

US3402430

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30

US3402430

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30

US3402430

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	23 Oct 2020 20:13:18

US3402430

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered empty.	(b) (4) Tammy Kohn (b) (4)	23 Oct 2020 20:13:18

US3402430

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	23 Oct 2020 20:13:39

US3402430

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User closed query 'Per GCL Lab Reconciliation: Per GCL, no immunogenicity sample was received for the Visit 3 Day 57 on 23OCT2020. Please clarify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 12:48:35
Query 'Per GCL Lab Reconciliation: Per GCL, no immunogenicity sample was received for the Visit 3 Day 57 on 23OCT2020. Please clarify and update as appropriate. ' answered with 'THE INFORMATION IS CORRECT. THE LAB TECH HAS ALREADY TAKEN CARE OF THE SAMPLE ISSUE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	02 Nov 2020 13:50:27
User opened query 'Per GCL Lab Reconciliation: Per GCL, no immunogenicity sample was received for the Visit 3 Day 57 on 23OCT2020. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 23:58:25
User entered '23 Oct 2020'	Tammy Kohn (b) (4) (b) (4)	23 Oct 2020 20:13:39

US3402430

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered '15:00'	(b) (4) Tammy Kohn (b) (4)	23 Oct 2020 20:13:39

US3402430

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered '23 Oct 2020 15:00'	System	23 Oct 2020 20:13:39

US3402430

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 18:28:35
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	23 Oct 2020 20:13:45

US3402430

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered '1'	System	23 Oct 2020 20:13:45

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 64'	System	22 Aug 2020 18:05:40

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-10-25T20:17:03', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'da49379e-776a-4f58-80b0-6a9ef149f017'	System	26 Oct 2020 00:17:27
User entered 'No (N)'	System	26 Oct 2020 00:17:27

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Have you been exposed to someone with 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)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-10-25T20:17:06', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'da49379e-776a-4f58-80b0-6a9ef149f017'	System	26 Oct 2020 00:17:27
User entered 'No (N)'	System	26 Oct 2020 00:17:27

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-10-25T20:17:25', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'da49379e-776a-4f58-80b0-6a9ef149f017'	System	26 Oct 2020 00:17:27
User entered '25 Oct 2020 20:17:25'	System	26 Oct 2020 00:17:27

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered '22 Oct 2020 00:01'	System	22 Aug 2020 18:05:40

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered '26 Oct 2020 23:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 71'	System	22 Aug 2020 18:05:40

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-10-30T06:59:23', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'b9aafcf6-9ad3-4298-a729-4c87849e26c4'	System	30 Oct 2020 10:59:37
User entered 'No (N)'	System	30 Oct 2020 10:59:37

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Have you been exposed to someone with 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)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-10-30T06:59:27', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'b9aafcf6-9ad3-4298-a729-4c87849e26c4'	System	30 Oct 2020 10:59:37
User entered 'No (N)'	System	30 Oct 2020 10:59:37

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-10-30T06:59:32', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'b9aafcf6-9ad3-4298-a729-4c87849e26c4'	System	30 Oct 2020 10:59:37
User entered '30 Oct 2020 06:59:32'	System	30 Oct 2020 10:59:37

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered '29 Oct 2020 00:01'	System	22 Aug 2020 18:05:40

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered '02 Nov 2020 23:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 78'	System	22 Aug 2020 18:05:40

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-11-05T06:09:50', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '27e7baa7-6c99-4daa-a530-551317504e21'	System	05 Nov 2020 11:10:10
User entered 'No (N)'	System	05 Nov 2020 11:10:10

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Have you been exposed to someone with 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)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-11-05T06:09:58', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '27e7baa7-6c99-4daa-a530-551317504e21'	System	05 Nov 2020 11:10:10
User entered 'No (N)'	System	05 Nov 2020 11:10:10

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-11-05T06:10:03', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '27e7baa7-6c99-4daa-a530-551317504e21' User entered '05 Nov 2020 06:10:03'	System	05 Nov 2020 11:10:10
	System	05 Nov 2020 11:10:10

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered '05 Nov 2020 00:01'	System	22 Aug 2020 18:05:40

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered '09 Nov 2020 23:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered 'Day 92'	System	22 Aug 2020 18:05:40

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-11-19T17:19:13', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'f7d64600-9b7c-4764-a3ce-89932a5c74fa'	System	19 Nov 2020 22:19:30
User entered 'No (N)'	System	19 Nov 2020 22:19:30

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Have you been exposed to someone with 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)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-11-19T17:19:23', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'f7d64600-9b7c-4764-a3ce-89932a5c74fa'	System	19 Nov 2020 22:19:30
User entered 'No (N)'	System	19 Nov 2020 22:19:30

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-11-19T17:19:25', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'f7d64600-9b7c-4764-a3ce-89932a5c74fa'	System	19 Nov 2020 22:19:30
User entered '19 Nov 2020 17:19:25'	System	19 Nov 2020 22:19:30

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered '19 Nov 2020 00:01'	System	22 Aug 2020 18:05:40

US3402430

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:53:27
Data entry locked.	System	22 Aug 2020 18:05:40
User entered '23 Nov 2020 23:59'	System	22 Aug 2020 18:05:40

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2020-11-25T12:27:06', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '46d8135a-833c-4df5-83c0-3bb37d52bbb8'	System	25 Nov 2020 17:27:14
User entered 'No (N)'	System	25 Nov 2020 17:27:14

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2020-11-25T12:27:09', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '46d8135a-833c-4df5-83c0-3bb37d52bbb8'	System	25 Nov 2020 17:27:14
User entered 'No (N)'	System	25 Nov 2020 17:27:14

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-11-25T12:27:12', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '46d8135a-833c-4df5-83c0-3bb37d52bbb8'	System	25 Nov 2020 17:27:14
User entered '25 Nov 2020 12:27:12'	System	25 Nov 2020 17:27:14

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2020-11-30T20:26:02', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6e62654f-a766-4696-9964-fa45d545b1a9'	System	01 Dec 2020 01:26:21
User entered 'No (N)'	System	01 Dec 2020 01:26:21

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2020-11-30T20:26:08', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6e62654f-a766-4696-9964-fa45d545b1a9'	System	01 Dec 2020 01:26:21
User entered 'No (N)'	System	01 Dec 2020 01:26:21

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-11-30T20:26:16', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6e62654f-a766-4696-9964-fa45d545b1a9'	System	01 Dec 2020 01:26:21
User entered '30 Nov 2020 20:26:16'	System	01 Dec 2020 01:26:21

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2020-12-07T15:54:34', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '65049e6a-03aa-4b03-9a79-1972b71f0986'	System	07 Dec 2020 20:55:00
User entered 'No (N)'	System	07 Dec 2020 20:55:00

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2020-12-07T15:54:54', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '65049e6a-03aa-4b03-9a79-1972b71f0986'	System	07 Dec 2020 20:55:00
User entered 'No (N)'	System	07 Dec 2020 20:55:00

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-12-07T15:54:56', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '65049e6a-03aa-4b03-9a79-1972b71f0986'	System	07 Dec 2020 20:55:00
User entered '07 Dec 2020 15:54:56'	System	07 Dec 2020 20:55:00

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2020-12-14T17:53:21', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'd0ac111a-f631-4d08-8f34-013554a2bc60'	System	14 Dec 2020 22:53:43
User entered 'No (N)'	System	14 Dec 2020 22:53:43

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2020-12-14T17:53:25', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'd0ac111a-f631-4d08-8f34-013554a2bc60'	System	14 Dec 2020 22:53:43
User entered 'No (N)'	System	14 Dec 2020 22:53:43

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-12-14T17:53:40', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'd0ac111a-f631-4d08-8f34-013554a2bc60'	System	14 Dec 2020 22:53:43
User entered '14 Dec 2020 17:53:40'	System	14 Dec 2020 22:53:43

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2020-12-21T05:19:46', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '5ca0472d-1657-422c-8928-85c439d8fd58'	System	21 Dec 2020 10:19:55
User entered 'No (N)'	System	21 Dec 2020 10:19:55

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2020-12-21T05:19:49', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '5ca0472d-1657-422c-8928-85c439d8fd58'	System	21 Dec 2020 10:19:55
User entered 'No (N)'	System	21 Dec 2020 10:19:55

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-12-21T05:19:51', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '5ca0472d-1657-422c-8928-85c439d8fd58'	System	21 Dec 2020 10:19:55
User entered '21 Dec 2020 05:19:51'	System	21 Dec 2020 10:19:55

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2020-12-28T19:12:44', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '3eea92f4-6733-430b-8f04-c4d261cc59ab'	System	29 Dec 2020 00:12:55
User entered 'No (N)'	System	29 Dec 2020 00:12:55

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2020-12-28T19:12:47', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '3eea92f4-6733-430b-8f04-c4d261cc59ab'	System	29 Dec 2020 00:12:55
User entered 'No (N)'	System	29 Dec 2020 00:12:55

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2020-12-28T19:12:50', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '3eea92f4-6733-430b-8f04-c4d261cc59ab'	System	29 Dec 2020 00:12:55
User entered '28 Dec 2020 19:12:50'	System	29 Dec 2020 00:12:55

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2021-01-05T16:28:21', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6eb5461d-53ac-4229-9839-56b0601e105e'	System	05 Jan 2021 21:28:31
User entered 'No (N)'	System	05 Jan 2021 21:28:31

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2021-01-05T16:28:25', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6eb5461d-53ac-4229-9839-56b0601e105e'	System	05 Jan 2021 21:28:31
User entered 'No (N)'	System	05 Jan 2021 21:28:31

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-01-05T16:28:27', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '6eb5461d-53ac-4229-9839-56b0601e105e' User entered '05 Jan 2021 16:28:27'	System	05 Jan 2021 21:28:31
	System	05 Jan 2021 21:28:31

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2021-01-11T18:35:41', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '1bc5822c-fbeb-43bb-b868-68e000971bd1'	System	11 Jan 2021 23:35:49
User entered 'No (N)'	System	11 Jan 2021 23:35:49

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2021-01-11T18:35:44', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '1bc5822c-fbeb-43bb-b868-68e000971bd1'	System	11 Jan 2021 23:35:49
User entered 'No (N)'	System	11 Jan 2021 23:35:49

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-01-11T18:35:46', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '1bc5822c-fbeb-43bb-b868-68e000971bd1' User entered '11 Jan 2021 18:35:46'	System	11 Jan 2021 23:35:49
	System	11 Jan 2021 23:35:49

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2021-01-20T13:26:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '39eda9de-1ef9-4103-8e55-e5c7a3018f8c'	System	20 Jan 2021 18:26:19
User entered 'No (N)'	System	20 Jan 2021 18:26:19

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2021-01-20T13:26:06', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '39eda9de-1ef9-4103-8e55-e5c7a3018f8c'	System	20 Jan 2021 18:26:19
User entered 'No (N)'	System	20 Jan 2021 18:26:19

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-01-20T13:26:16', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '39eda9de-1ef9-4103-8e55-e5c7a3018f8c'	System	20 Jan 2021 18:26:19
User entered '20 Jan 2021 13:26:16'	System	20 Jan 2021 18:26:19

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2021-01-26T12:21:35', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'b3fd4973-532a-4717-8cee-16f1e35437b9'	System	26 Jan 2021 17:46:11
User entered 'No (N)'	System	26 Jan 2021 17:46:11

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2021-01-26T12:21:41', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'b3fd4973-532a-4717-8cee-16f1e35437b9'	System	26 Jan 2021 17:46:11
User entered 'No (N)'	System	26 Jan 2021 17:46:11

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-01-26T12:21:44', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'b3fd4973-532a-4717-8cee-16f1e35437b9' User entered '26 Jan 2021 12:21:44'	System	26 Jan 2021 17:46:11
	System	26 Jan 2021 17:46:11

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2021-02-01T16:14:14', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '88d5bb80-b2a7-46e7-9b08-12edf26f270d'	System	01 Feb 2021 21:14:24
User entered 'No (N)'	System	01 Feb 2021 21:14:24

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2021-02-01T16:14:18', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '88d5bb80-b2a7-46e7-9b08-12edf26f270d'	System	01 Feb 2021 21:14:24
User entered 'No (N)'	System	01 Feb 2021 21:14:24

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-02-01T16:14:21', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '88d5bb80-b2a7-46e7-9b08-12edf26f270d'	System	01 Feb 2021 21:14:24
User entered '01 Feb 2021 16:14:21'	System	01 Feb 2021 21:14:24

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2021-02-08T06:02:26', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '69677bce-fec2-4024-bce4-5b67a0cbf7eb'	System	08 Feb 2021 11:02:35
User entered 'No (N)'	System	08 Feb 2021 11:02:35

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2021-02-08T06:02:29', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '69677bce-fec2-4024-bce4-5b67a0cbf7eb'	System	08 Feb 2021 11:02:35
User entered 'No (N)'	System	08 Feb 2021 11:02:35

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-02-08T06:02:32', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '69677bce-fec2-4024-bce4-5b67a0cbf7eb'	System	08 Feb 2021 11:02:35
User entered '08 Feb 2021 06:02:32'	System	08 Feb 2021 11:02:35

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2021-02-17T10:55:43', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'e6cb9c32-6de2-4895-81f7-2cb3a8e365d5'	System	17 Feb 2021 15:55:51
User entered 'No (N)'	System	17 Feb 2021 15:55:51

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2021-02-17T10:55:45', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'e6cb9c32-6de2-4895-81f7-2cb3a8e365d5'	System	17 Feb 2021 15:55:51
User entered 'No (N)'	System	17 Feb 2021 15:55:51

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-02-17T10:55:48', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'e6cb9c32-6de2-4895-81f7-2cb3a8e365d5' User entered '17 Feb 2021 10:55:48'	System	17 Feb 2021 15:55:51
	System	17 Feb 2021 15:55:51

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2021-02-22T18:07:30', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '005e7a78-c8ee-460f-9795-ac8214978e47'	System	22 Feb 2021 23:12:14
User entered 'No (N)'	System	22 Feb 2021 23:12:14

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2021-02-22T18:07:33', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '005e7a78-c8ee-460f-9795-ac8214978e47'	System	22 Feb 2021 23:12:14
User entered 'No (N)'	System	22 Feb 2021 23:12:14

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-02-22T18:07:36', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '005e7a78-c8ee-460f-9795-ac8214978e47'	System	22 Feb 2021 23:12:14
User entered '22 Feb 2021 18:07:36'	System	22 Feb 2021 23:12:14

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2021-03-01T06:53:02-05:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '26ca6f75-eba7-461b-b0ed-71984ffa640f' User entered 'No (N)'	System	01 Mar 2021 11:53:11
	System	01 Mar 2021 11:53:11

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2021-03-01T06:53:05-05:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '26ca6f75-eba7-461b-b0ed-71984ffa640f'	System	01 Mar 2021 11:53:11
User entered 'No (N)'	System	01 Mar 2021 11:53:11

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-03-01T06:53:07-05:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '26ca6f75-eba7-461b-b0ed-71984ffa640f' User entered '01 Mar 2021 06:53:07'	System	01 Mar 2021 11:53:11
	System	01 Mar 2021 11:53:11

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2021-03-10T14:33:20-05:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '444dd0f3-a768-4937-99d0-0efc6a7e475c' User entered 'No (N)'	System	10 Mar 2021 19:34:13
	System	10 Mar 2021 19:34:13

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2021-03-10T14:33:57-05:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '444dd0f3-a768-4937-99d0-0efc6a7e475c'	System	10 Mar 2021 19:34:13
User entered 'No (N)'	System	10 Mar 2021 19:34:13

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-03-10T14:34:07-05:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '444dd0f3-a768-4937-99d0-0efc6a7e475c' User entered '10 Mar 2021 14:34:07'	System	10 Mar 2021 19:34:13
	System	10 Mar 2021 19:34:13

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2021-03-16T16:32:56-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '1c8ff66d-c215-4008-bce9-a236805ec362'	System	16 Mar 2021 20:33:06
User entered 'No (N)'	System	16 Mar 2021 20:33:06

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2021-03-16T16:32:59-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '1c8ff66d-c215-4008-bce9-a236805ec362'	System	16 Mar 2021 20:33:06
User entered 'No (N)'	System	16 Mar 2021 20:33:06

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-03-16T16:33:02-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '1c8ff66d-c215-4008-bce9-a236805ec362'	System	16 Mar 2021 20:33:06
User entered '16 Mar 2021 16:33:02'	System	16 Mar 2021 20:33:06

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2021-03-22T18:50:28-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '742c2ca0-e81b-4bf1-8ea8-a31b94ee6d5b'	System	22 Mar 2021 22:50:39
User entered 'No (N)'	System	22 Mar 2021 22:50:39

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2021-03-22T18:50:31-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '742c2ca0-e81b-4bf1-8ea8-a31b94ee6d5b'	System	22 Mar 2021 22:50:39
User entered 'No (N)'	System	22 Mar 2021 22:50:39

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-03-22T18:50:33-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '742c2ca0-e81b-4bf1-8ea8-a31b94ee6d5b' User entered '22 Mar 2021 18:50:33'	System	22 Mar 2021 22:50:39

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2021-03-29T17:58:54-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '48b85734-9360-4edb-9da4-367cfd43183f'	System	29 Mar 2021 21:59:03
User entered 'No (N)'	System	29 Mar 2021 21:59:03

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2021-03-29T17:58:56-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '48b85734-9360-4edb-9da4-367cfd43183f'	System	29 Mar 2021 21:59:03
User entered 'No (N)'	System	29 Mar 2021 21:59:03

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-03-29T17:58:59-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '48b85734-9360-4edb-9da4-367cfd43183f' User entered '29 Mar 2021 17:58:59'	System	29 Mar 2021 21:59:03
	System	29 Mar 2021 21:59:03

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2021-04-06T07:08:16-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '8771e6df-78bb-4307-8762-cc2c0e7cbc2a' User entered 'No (N)'	System	06 Apr 2021 11:08:28
	System	06 Apr 2021 11:08:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2021-04-06T07:08:21-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '8771e6df-78bb-4307-8762-cc2c0e7cbc2a'	System	06 Apr 2021 11:08:28
User entered 'No (N)'	System	06 Apr 2021 11:08:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-04-06T07:08:23-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '8771e6df-78bb-4307-8762-cc2c0e7cbc2a' User entered '06 Apr 2021 07:08:23'	System	06 Apr 2021 11:08:28
	System	06 Apr 2021 11:08:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2021-04-14T12:34:03-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '0e85c97b-098e-419b-8fe9-40b121b81739'	System	14 Apr 2021 17:53:01
User entered 'No (N)'	System	14 Apr 2021 17:53:01

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2021-04-14T12:34:07-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '0e85c97b-098e-419b-8fe9-40b121b81739'	System	14 Apr 2021 17:53:01
User entered 'No (N)'	System	14 Apr 2021 17:53:01

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-04-14T12:34:09-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '0e85c97b-098e-419b-8fe9-40b121b81739'	System	14 Apr 2021 17:53:01
User entered '14 Apr 2021 12:34:09'	System	14 Apr 2021 17:53:01

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2021-04-20T22:51:48-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'c96cdc31-af73-414f-9ce6-08d6529f352d' User entered 'No (N)'	System	21 Apr 2021 02:53:42
	System	21 Apr 2021 02:53:42

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2021-04-20T22:51:51-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'c96cdc31-af73-414f-9ce6-08d6529f352d'	System	21 Apr 2021 02:53:42
User entered 'No (N)'	System	21 Apr 2021 02:53:42

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-04-20T22:51:53-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'c96cdc31-af73-414f-9ce6-08d6529f352d'	System	21 Apr 2021 02:53:42
User entered '20 Apr 2021 22:51:53'	System	21 Apr 2021 02:53:42

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2021-04-26T18:18:22-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '66594e57-8b3c-4f84-aa24-5a60f875abf4' User entered 'No (N)'	System	26 Apr 2021 22:18:37
	System	26 Apr 2021 22:18:37

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2021-04-26T18:18:25-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '66594e57-8b3c-4f84-aa24-5a60f875abf4'	System	26 Apr 2021 22:18:37
User entered 'No (N)'	System	26 Apr 2021 22:18:37

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-04-26T18:18:28-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '66594e57-8b3c-4f84-aa24-5a60f875abf4'	System	26 Apr 2021 22:18:37
User entered '26 Apr 2021 18:18:28'	System	26 Apr 2021 22:18:37

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[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 (2cb388965df3749e)', Time: '2021-05-03T21:53:05-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '721effe7-7cf7-4497-ba51-bf62feecc241'	System	04 May 2021 01:53:18
User entered 'No (N)'	System	04 May 2021 01:53:18

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with 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 (2cb388965df3749e)', Time: '2021-05-03T21:53:09-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '721effe7-7cf7-4497-ba51-bf62feecc241'	System	04 May 2021 01:53:18
User entered 'No (N)'	System	04 May 2021 01:53:18

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-05-03T21:53:11-04:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: '721effe7-7cf7-4497-ba51-bf62feecc241'	System	04 May 2021 01:53:18
User entered '03 May 2021 21:53:11'	System	04 May 2021 01:53:18

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 01:20:28

US3402430

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:20:28
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 01:20:28

US3402430

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:38:39

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)	25 Apr 2021 22:12:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-02-27T17:15:30-05:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'ec17d056-33db-4add-8137-a8807ca17579'	System	27 Feb 2021 22:15:38
User entered 'No (N)'	System	27 Feb 2021 22:15:38

US3402430

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:38:39

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:12:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2cb388965df3749e)', Time: '2021-02-27T17:15:36-05:00', User OID: 'PatientReportedOutcome (US3402430)', ODM File OID: 'ec17d056-33db-4add-8137-a8807ca17579' User entered '27 Feb 2021 17:15:36'	System	27 Feb 2021 22:15:38
	System	27 Feb 2021 22:15:38

US3402430

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:34:25
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	16 Nov 2020 15:04:52

US3402430

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:34:25
User entered '16 Nov 2020'	Tammy Kohn (b) (4)	16 Nov 2020 15:04:52

US3402430

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:34:25
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4)	16 Nov 2020 15:04:52

US3402430

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:34:25
User entered empty.	Tammy Kohn (b) (4)	16 Nov 2020 15:04:52

US3402430

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:34:25
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	16 Nov 2020 15:05:08

US3402430

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:05:30
User entered 'I'	System	16 Nov 2020 15:05:08

US3402430

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	04 Feb 2021 21:23:54
	(b) (4)	

US3402430

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
	(b) (4)	
User entered '18 Dec 2020'	Tammy Kohn (b) (4)	04 Feb 2021 21:23:54
	(b) (4)	

US3402430

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4)	04 Feb 2021 21:23:54
	(b) (4)	

US3402430

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	04 Feb 2021 21:23:54
	(b) (4)	

US3402430

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 19:50:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	04 Feb 2021 21:24:00

US3402430

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:16
User entered 'I'	System	04 Feb 2021 21:24:00

US3402430

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 19:50:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	04 Feb 2021 21:32:41

US3402430

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
	(b) (4)	
User entered '18 Jan 2021'	Tammy Kohn (b) (4)	04 Feb 2021 21:32:41
	(b) (4)	

US3402430

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	29 Apr 2021 19:50:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:57:22
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	04 Feb 2021 21:32:41

US3402430

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	04 Feb 2021 21:32:41
	(b) (4)	

US3402430

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	04 Feb 2021 21:32:46
	(b) (4)	

US3402430

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:16
User entered 'I'	System	04 Feb 2021 21:32:46

US3402430

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	15 Feb 2021 17:02:07
	(b) (4)	

US3402430

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
	(b) (4)	
User entered '15 Feb 2021'	Traci Hull (b) (4)	15 Feb 2021 17:02:07
	(b) (4)	

US3402430

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	29 Apr 2021 19:50:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:57:22
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	15 Feb 2021 17:02:07

US3402430

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	15 Feb 2021 17:02:07
	(b) (4)	

US3402430

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	15 Feb 2021 17:02:11
	(b) (4)	

US3402430

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:50:16
User entered 'I'	System	15 Feb 2021 17:02:11

US3402430

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:31:59

US3402430

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '23 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:31:59
	(b) (4)	

US3402430

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[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 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Clinic (Clinic)'	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:31:59

US3402430

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User entered 'VISIT4'	System	24 Mar 2021 12:31:59

US3402430

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 16:25:14
	(b) (4)	

US3402430

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 16:25:14

US3402430

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 16:25:14

US3402430

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User entered empty.	System	31 Mar 2021 16:25:14

US3402430

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 16:25:14
	(b) (4)	

US3402430

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 16:25:14
	(b) (4)	

US3402430

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 16:25:14

US3402430

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 16:25:14

US3402430

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User entered empty.	System	31 Mar 2021 16:25:14

US3402430

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 16:25:14

US3402430

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User entered empty.	System	31 Mar 2021 16:25:14

US3402430

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 16:25:14

US3402430

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User entered empty.	System	31 Mar 2021 16:25:14

US3402430

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 16:25:14
	(b) (4)	

US3402430

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User entered empty.	System	31 Mar 2021 16:25:14

US3402430

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11

US3402430

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11

US3402430

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:32:04
	(b) (4)	

US3402430

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:32:04

US3402430

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:32:16

US3402430

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '23 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:32:16
	(b) (4)	

US3402430

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '13:16'	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:32:16

US3402430

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User entered '23 Mar 2021 13:16'	System	24 Mar 2021 12:32:16

US3402430

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:34:56

US3402430

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:11:11
User entered 'I'	System	24 Mar 2021 12:34:56

US3402430

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	16 Apr 2021 15:14:38
	(b) (4)	

US3402430

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
	(b) (4)	
User entered '16 Apr 2021'	Traci Hull (b) (4)	16 Apr 2021 15:14:38
	(b) (4)	

US3402430

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4) (b) (4)	16 Apr 2021 15:14:38

US3402430

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	16 Apr 2021 15:14:38
	(b) (4)	

US3402430

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	16 Apr 2021 15:14:42
	(b) (4)	

US3402430

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 15:14:42

US3402430

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

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:00:59

US3402430

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

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '28 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	28 Jan 2021 15:00:59
	(b) (4)	

US3402430

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

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[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 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	28 Jan 2021 15:00:59

US3402430

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

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 15:00:59

US3402430

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:39

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '06 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	28 Jan 2021 15:01:49
	(b) (4)	

US3402430

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:39

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '0'	(b) (4) Tammy Kohn (b) (4)	09 Apr 2021 14:17:49
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 13:40:07

US3402430

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:39

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:01:49

US3402430

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:39

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Apr 2021 06:11:46
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 14:17:52
User entered 'Amendment 6 or later (Amendment 6 or later)'	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 14:17:49
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:11:54
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:40:07

US3402430

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:39

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '28 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	28 Jan 2021 15:01:49
	(b) (4)	

US3402430

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:39

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Placebo (Placebo)'	(b) (4) Traci Hull (b) (4) (b) (4)	28 Jan 2021 15:01:49

US3402430

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:39

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Placebo (Placebo)'	(b) (4) Traci Hull (b) (4) (b) (4)	28 Jan 2021 15:01:49

US3402430

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:39

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Placebo (Placebo)'	(b) (4) Traci Hull (b) (4) (b) (4)	28 Jan 2021 15:01:49

US3402430

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:39

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4)	28 Jan 2021 15:01:49
	Traci Hull (b) (4)	
	(b) (4)	

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:39

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered '1'	System	28 Jan 2021 15:01:49

US3402430

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:39

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered 'I'	System	28 Jan 2021 15:01:49

US3402430

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered empty.	System	28 Jan 2021 15:03:46
DataPoint set to visible.	System	28 Jan 2021 15:01:49

US3402430

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered empty.	System	28 Jan 2021 15:03:46
DataPoint set to visible.	System	28 Jan 2021 15:01:49

US3402430

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '28 Jan 2021'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '08:19'	(b) (4)	28 Jan 2021 15:03:46
	Traci Hull (b) (4)	
	(b) (4)	

US3402430

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered '28 Jan 2021 08:19'	System	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '36.9' C	(b) (4)	
	Traci Hull (b) (4)	28 Jan 2021 15:03:46
	(b) (4)	

US3402430

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '68'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered 'bpm'	System	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '18'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered 'breaths/min'	System	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '130'	(b) (4)	
	Traci Hull (b) (4)	28 Jan 2021 15:03:46
	(b) (4)	

US3402430

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered 'mmHg'	System	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '72'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered 'mmHg'	System	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered empty.	System	28 Jan 2021 15:03:46
DataPoint set to visible.	System	28 Jan 2021 15:01:49

US3402430

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '28 Jan 2021'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '09:15'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered '28 Jan 2021 09:15'	System	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '36.7' C	(b) (4)	
	Traci Hull (b) (4)	28 Jan 2021 15:03:46
	(b) (4)	

US3402430

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '88'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered 'bpm'	System	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '18'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered 'breaths/min'	System	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '130'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered 'mmHg'	System	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '80'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:46

US3402430

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered 'mmHg'	System	28 Jan 2021 15:03:46

US3402430

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4)	28 Jan 2021 15:03:54
	Traci Hull (b) (4)	
	(b) (4)	

US3402430

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '28 Jan 2021'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:03:54

US3402430

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:04:18

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	28 Jan 2021 15:04:18
	(b) (4)	

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	Traci Hull (b) (4)	28 Jan 2021 15:04:18

US3402430

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered 'mRNA-1273'	System	28 Jan 2021 15:04:18
DataPoint set to visible.	System	28 Jan 2021 15:01:49

US3402430

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '28 Jan 2021'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:04:18

US3402430

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '08:41'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:04:18

US3402430

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered '28 Jan 2021 08:41'	System	28 Jan 2021 15:04:18

US3402430

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Left Arm (LEFT ARM)'	Traci Hull (b) (4)	28 Jan 2021 15:04:18

US3402430

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered 'ONCE'	System	28 Jan 2021 15:04:18

US3402430

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered 'INTRAMUSCULAR'	System	28 Jan 2021 15:04:18

US3402430

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:02:05

US3402430

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '28 Jan 2021'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:02:05

US3402430

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '08:14'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:02:05

US3402430

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered '28 Jan 2021 08:14'	System	28 Jan 2021 15:02:05

US3402430

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:38:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:02:19

US3402430

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '28 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	28 Jan 2021 15:02:19
	(b) (4)	

US3402430

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '08:10'	(b) (4) Traci Hull (b) (4) (b) (4)	28 Jan 2021 15:02:19

US3402430

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered '28 Jan 2021 08:10'	System	28 Jan 2021 15:02:19

US3402430

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

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	28 Jan 2021 15:02:23

US3402430

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

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered 'I'	System	28 Jan 2021 15:02:23

US3402430

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	04 Feb 2021 21:33:06

US3402430

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '4 Feb 2021'	(b) (4) Tammy Kohn (b) (4)	04 Feb 2021 21:33:06

US3402430

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tammy Kohn (b) (4)	04 Feb 2021 21:33:06

US3402430

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	04 Feb 2021 21:33:06
	(b) (4)	

US3402430

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	04 Feb 2021 21:33:11

US3402430

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered 'I'	System	04 Feb 2021 21:33:11

US3402430

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered 'I'	System	04 Feb 2021 21:33:11
DataPoint set to visible.	System	04 Feb 2021 21:33:11

US3402430

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4)	24 Feb 2021 14:59:00
	Traci Hull (b) (4)	
	(b) (4)	

US3402430

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '24 Feb 2021'	(b) (4)	
	Traci Hull (b) (4)	24 Feb 2021 14:59:00
	(b) (4)	

US3402430

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[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 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	24 Feb 2021 14:59:00

US3402430

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered 'OLD29'	System	24 Feb 2021 14:59:00

US3402430

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	24 Feb 2021 15:02:19

US3402430

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4)	24 Feb 2021 15:02:19
	Traci Hull (b) (4)	
	(b) (4)	

US3402430

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '24 Feb 2021'	(b) (4) Traci Hull (b) (4)	24 Feb 2021 15:02:19

US3402430

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '08:34'	(b) (4)	
	Traci Hull (b) (4)	24 Feb 2021 15:02:19
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered '24 Feb 2021 08:34'	System	24 Feb 2021 15:02:19

US3402430

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '36.5' C	(b) (4)	
	Traci Hull (b) (4)	24 Feb 2021 15:02:19
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	24 Feb 2021 15:02:19

US3402430

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Traci Hull (b) (4)	24 Feb 2021 15:02:19

US3402430

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '54'	(b) (4) Traci Hull (b) (4)	24 Feb 2021 15:02:19

US3402430

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered 'bpm'	System	24 Feb 2021 15:02:19

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '12'	(b) (4)	
	Traci Hull (b) (4)	24 Feb 2021 15:02:19
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered 'breaths/min'	System	24 Feb 2021 15:02:19

US3402430

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '125'	(b) (4)	
	Traci Hull (b) (4)	24 Feb 2021 15:02:19
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered 'mmHg'	System	24 Feb 2021 15:02:19

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '70'	(b) (4) Traci Hull (b) (4)	24 Feb 2021 15:02:19

US3402430

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered 'mmHg'	System	24 Feb 2021 15:02:19

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	24 Feb 2021 15:02:19

US3402430

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	24 Feb 2021 15:02:19

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '24 Feb 2021'	(b) (4) Traci Hull (b) (4)	24 Feb 2021 15:02:19

US3402430

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '09:21'	(b) (4) Traci Hull (b) (4)	24 Feb 2021 15:02:19

US3402430

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered '24 Feb 2021 09:21'	System	24 Feb 2021 15:02:19

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '36.4' C	(b) (4)	
	Traci Hull (b) (4)	24 Feb 2021 15:02:19
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	24 Feb 2021 15:02:19

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	24 Feb 2021 15:02:19
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '66'	(b) (4) Traci Hull (b) (4)	24 Feb 2021 15:02:19

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered 'bpm'	System	24 Feb 2021 15:02:19

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '12'	(b) (4) Traci Hull (b) (4)	24 Feb 2021 15:02:19

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered 'breaths/min'	System	24 Feb 2021 15:02:19

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '121'	(b) (4) Traci Hull (b) (4)	24 Feb 2021 15:02:19

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered 'mmHg'	System	24 Feb 2021 15:02:19

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '81'	(b) (4) Traci Hull (b) (4)	24 Feb 2021 15:02:19

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered 'mmHg'	System	24 Feb 2021 15:02:19

US3402430

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4)	24 Feb 2021 15:02:25
	Traci Hull (b) (4)	
	(b) (4)	

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Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '24 Feb 2021'	(b) (4)	
	Traci Hull (b) (4)	24 Feb 2021 15:02:25
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	24 Feb 2021 15:02:44

US3402430

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	24 Feb 2021 15:02:44
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	Traci Hull (b) (4)	24 Feb 2021 15:02:44

US3402430

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered 'mRNA-1273'	System	24 Feb 2021 15:02:44
DataPoint set to visible.	System	04 Feb 2021 21:33:11

US3402430

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '24 Feb 2021'	(b) (4) Traci Hull (b) (4)	24 Feb 2021 15:02:44

US3402430

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '08:50'	(b) (4)	
	Traci Hull (b) (4)	24 Feb 2021 15:02:44
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered '24 Feb 2021 08:50'	System	24 Feb 2021 15:02:44

US3402430

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Left Arm (LEFT ARM)'	Traci Hull (b) (4)	24 Feb 2021 15:02:44

US3402430

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered 'ONCE'	System	24 Feb 2021 15:02:44

US3402430

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered 'INTRAMUSCULAR'	System	24 Feb 2021 15:02:44

US3402430

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	24 Feb 2021 15:02:48
	(b) (4)	

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered 'I'	System	24 Feb 2021 15:02:48

US3402430

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4)	04 Mar 2021 13:36:09
	Traci Hull (b) (4)	
	(b) (4)	

US3402430

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '3 Mar 2021'	(b) (4) Traci Hull (b) (4) (b) (4)	04 Mar 2021 13:36:09

US3402430

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	04 Mar 2021 13:36:09

US3402430

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	04 Mar 2021 13:36:09
	(b) (4)	

US3402430

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	04 Mar 2021 13:35:54

US3402430

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:57
User entered 'I'	System	04 Mar 2021 13:35:54

US3402430

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:30:57

US3402430

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '23 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:30:57
	(b) (4)	

US3402430

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[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 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Clinic (Clinic)'	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:30:57

US3402430

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered 'OLD57'	System	24 Mar 2021 12:30:57

US3402430

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:31:14

US3402430

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:31:14

US3402430

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:31:14

US3402430

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered empty.	System	24 Mar 2021 12:31:14

US3402430

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:31:14

US3402430

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:31:14

US3402430

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:31:14

US3402430

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:31:14

US3402430

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered empty.	System	24 Mar 2021 12:31:14

US3402430

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:31:14

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered empty.	System	24 Mar 2021 12:31:14

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:31:14

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered empty.	System	24 Mar 2021 12:31:14

US3402430

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:31:14

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered empty.	System	24 Mar 2021 12:31:14

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:31:18

US3402430

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered empty.	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:31:18

US3402430

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:31:30

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '23 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:31:30
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
User entered '13:16'	(b) (4) Tammy Kohn (b) (4)	24 Mar 2021 12:31:30

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:13:40
User entered '23 Mar 2021 13:16'	System	24 Mar 2021 12:31:30

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:38:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:06:34
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	18 Sep 2020 17:27:41
User entered 'No (N)'	Traci Hull (b) (4)	24 Aug 2020 11:44:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 17:31:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 17:31:43
	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 17:30:39
User entered 'HYPERTENSION'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:15
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:20
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 17:30:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 17:30:58
User entered '14 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	18 Sep 2020 17:30:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 17:30:07
User entered empty.	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:22
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:30:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	18 Sep 2020 17:30:58
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	18 Sep 2020 17:30:07
User entered 'Yes (Y)'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	18 Sep 2020 17:30:58
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	18 Sep 2020 17:30:58
User entered empty; reason for change New Information	Traci Hull (b) (4)	18 Sep 2020 17:30:58
	(b) (4)	
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	18 Sep 2020 17:30:07
User entered '14 Sep 2020'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:26
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:30:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered '0'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:33
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered '0'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered '0'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:39
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:42
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered '0'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered '0'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered '0'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered 'Related (RELATED)'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User closed query 'Per CDM: please consider updating this to IP Withdrawal since Day 29 dose was not given due to this adverse event.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:11:41
Query 'Per CDM: please consider updating this to IP Withdrawal since Day 29 dose was not given due to this adverse event.' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4)	23 Nov 2020 21:13:16
	(b) (4)	
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	23 Nov 2020 21:13:11
	(b) (4)	
User opened query 'Per CDM: please consider updating this to IP Withdrawal since Day 29 dose was not given due to this adverse event.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:18:00
User entered 'None (NONE)'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[None](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered '0'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:58
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered 'I'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

US3402430

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:53:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered '0'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

US3402430

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:53:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

US3402430

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:53:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

US3402430

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:33
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:52:26
	(b) (4)	
User entered 'SUBJECT DID NOT RECEIVE 2ND VACCINATION DUE TO HYPERTENSION AE. SUBJECT WILL REMAIN IN STUDY FOR SAFETY INFORMATION.' reason for change: Data Entry Error	Tammy Kohn (b) (4)	18 Nov 2020 15:49:28
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	18 Sep 2020 17:30:07
	(b) (4)	

US3402430

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 17:30:07

US3402430

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 17:30:07

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:06:34
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:52:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:50:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4)	18 Sep 2020 17:31:23
User entered 'No (N)'	Traci Hull (b) (4)	24 Aug 2020 11:45:32

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 17:34:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 17:34:37
Data point term sent to Coder	System	18 Sep 2020 17:33:50
User entered 'hydrochlorothiazide'	Traci Hull (b) (4) (b) (4)	18 Sep 2020 17:32:50

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	18 Sep 2020 17:32:50
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered 'HYPERTENSION'	Traci Hull (b) (4)	18 Sep 2020 17:32:50
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered '25'	Traci Hull (b) (4)	18 Sep 2020 17:32:50
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered 'mg (mg)'	Traci Hull (b) (4)	18 Sep 2020 17:32:50
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	18 Sep 2020 17:32:50
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered 'once daily (QD)'	Traci Hull (b) (4)	18 Sep 2020 17:32:50
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	18 Sep 2020 17:32:50
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	18 Sep 2020 17:32:50
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	18 Sep 2020 17:32:50
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered '17 Sep 2020'	Traci Hull (b) (4)	18 Sep 2020 17:32:50
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered '0'	Traci Hull (b) (4)	18 Sep 2020 17:32:50
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	18 Sep 2020 17:32:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	18 Sep 2020 17:32:50
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	18 Sep 2020 17:32:50
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:32:50

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:32:50

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 17:32:50

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Oct 2020 21:36:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 21:36:44
Data point term sent to Coder	System	07 Oct 2020 20:49:06
User entered 'Lisinopril'	Abigail Wine (b) (4) (b) (4)	07 Oct 2020 20:48:38

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered 'No (N)'	Abigail Wine (b) (4)	07 Oct 2020 20:48:38
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
User entered 'Hypertension'	(b) (4) Abigail Wine (b) (4)	07 Oct 2020 20:48:38

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered '10'	Abigail Wine (b) (4)	07 Oct 2020 20:48:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered 'mg (mg)'	Abigail Wine (b) (4)	07 Oct 2020 20:48:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered empty.	Abigail Wine (b) (4)	07 Oct 2020 20:48:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered 'once daily (QD)'	Abigail Wine (b) (4)	07 Oct 2020 20:48:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered empty.	Abigail Wine (b) (4)	07 Oct 2020 20:48:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered 'Oral (ORAL)'	Abigail Wine (b) (4)	07 Oct 2020 20:48:38
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered empty.	Abigail Wine (b) (4)	07 Oct 2020 20:48:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered '20 Sep 2020'	Abigail Wine (b) (4)	07 Oct 2020 20:48:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered '0'	Abigail Wine (b) (4)	07 Oct 2020 20:48:38
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered 'Yes (Y)'	Abigail Wine (b) (4)	07 Oct 2020 20:48:38
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:39

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered empty.	Abigail Wine (b) (4)	07 Oct 2020 20:48:38
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered 'No (N)'	Abigail Wine (b) (4)	07 Oct 2020 20:48:38
	(b) (4)	

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 20:48:38

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 20:48:38

US3402430

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 20:48:38

US3402430

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:38:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:44:48
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	24 Aug 2020 11:44:32
	(b) (4)	

US3402430

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:38:39

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:59:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:53:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:49:58
User entered '21 Sep 2020'	Jennifer Molstead (b) (4)	15 Oct 2020 12:30:58

US3402430

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:38:39

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:59:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:53:24
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:49:58
User closed query 'Per CDM: Per this form the AE is recorded as reason for dose discontinuation; however action taken with investigational product is not recorded as IP withdrawn. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:16:24
Query 'Per CDM: Per this form the AE is recorded as reason for dose discontinuation; however action taken with investigational product is not recorded as IP withdrawn. Please review and reconcile.' answered with 'Patient has been withdrawn from further vaccination due to blood pressure being to high. patient will remain in the study for follow up only' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	20 Nov 2020 19:13:18
User opened query 'Per CDM: Per this form the AE is recorded as reason for dose discontinuation; however action taken with investigational product is not recorded as IP withdrawn. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 17:48:20
User entered 'AE (specify) (ADVERSE EVENT)'	Jennifer Molstead (b) (4) (b) (4)	15 Oct 2020 12:30:58

US3402430

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:38:39

If reason is AE, SAE, 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 07:59:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:57:22
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:53:26
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:49:58
User closed query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 07:15:26
Query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' answered with 'Information has been updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	02 Mar 2021 20:46:04
User entered 'AE #1' reason for change: Per Query Resolution	Tammy Kohn (b) (4) (b) (4)	02 Mar 2021 20:46:01
User opened query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:45:54
User closed query 'Per CDM: thank you for the update, please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) and remove the details' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:33:30
Query 'Per CDM: thank you for the update, please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) and remove the details' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 21:14:10
User entered 'AE 1' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 21:14:03
User opened query 'Per CDM: thank you for the update, please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) and remove the details' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:47:28
Query 'Per CDM Re-Query: thank you for the update however, please consider removing the details as per CCGs. ' canceled (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:46:56

US3402430

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:38:39

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User opened query 'Per CDM Re-Query: thank you for the update however, please consider removing the details as per CCGs. ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:16:17
User closed query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:16:17
User entered 'AE 1 HYPERTENSION SUBJECT WILL REMAIN IN STUDY FOR FOLLOW UP PURPOSES ONLY.' reason for change: Data Entry Error	Tammy Kohn (b) (4)	20 Nov 2020 19:13:42
User entered 'AE 1 Hypertension' reason for change: Data Entry Error	Tammy Kohn (b) (4)	20 Nov 2020 19:08:21
Query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' answered with 'UPDATED TO AE #1' (Site from DM).	Tammy Kohn (b) (4)	18 Nov 2020 15:48:59
User entered 'AE 1' reason for change: Data Entry Error	Tammy Kohn (b) (4)	18 Nov 2020 15:48:49
User opened query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:03:27
User entered 'Subject did not receive 2nd vaccination due to hypertension AE. Subject will remain in study for safety information.'	Jennifer Molstead (b) (4)	15 Oct 2020 12:30:58