

US3522664 (Prod: Henry Ford Health System)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:53:30

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US3522664

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 19:17:32

Generated On: 11 Aug 2021 22:53:30

Participant ID

US3522664

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

US3522664

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:17:34

Generated On: 11 Aug 2021 22:53:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	62
Age Units	YEARS
Age (Derived)	62
Sex	Female <input type="checkbox"/> Male <input checked="" type="checkbox"/>
Ethnicity	Hispanic or Latino <input checked="" type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Not Reported <input type="checkbox"/> Unknown <input type="checkbox"/>
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) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Date of Informed Consent (<i>dd MMM yyyy</i>)	11 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 19:17:34

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 19:17:34

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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) 09 Mar 2021 15:42:09

Generated On: 11 Aug 2021 22:53:30

Condition	GERD
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Mar 2021 15:42:09

Generated On: 11 Aug 2021 22:53:30

Condition	COSMETIC FACIAL BOTOX (FOREHEAD AND BROW)
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 09 Mar 2021 15:42:09

Generated On: 11 Aug 2021 22:53:30

Condition	COSMETIC DERMAL FILLER (BELOW ORBS OF THE EYES AND TO CREASES AROUND THE MOUTH)
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 19:17:34

Generated On: 11 Aug 2021 22:53:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:23 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:23
Height (<i>xxx.x</i>)	70 in
Weight (<i>xxx.x</i>)	177 lb
BMI (<i>xxx.x</i>)	25.44996 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) 05 Mar 2021 19:17:34

Generated On: 11 Aug 2021 22:53:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 19:17:34

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 19:17:34

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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) 16 Feb 2021 19:25:39

Generated On: 11 Aug 2021 22:53:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 19:25:38

Generated On: 11 Aug 2021 22:53:30

What was the date of randomization? (dd MMM yyyy) 11 SEP 2020

What was the participant's randomization number? 113425

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) 16 Feb 2021 19:25:39

Generated On: 11 Aug 2021 22:53:30

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) 16 Feb 2021 19:25:39

Generated On: 11 Aug 2021 22:53:30

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)	11 SEP 2020
Time of assessment (00:00-23:59)	12:23 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:23
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 19:25:39

Generated On: 11 Aug 2021 22:53:30

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)	11 SEP 2020
Time of assessment (00:00-23:59)	13:53 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 13:53
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:25:38

Generated On: 11 Aug 2021 22:53:30

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 19:25:38

Generated On: 11 Aug 2021 22:53:30

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) 11 SEP 2020

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

Treatment Date and Time (derived) 11 SEP 2020 13:23

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) 16 Feb 2021 19:25:38

Generated On: 11 Aug 2021 22:53:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 SEP 2020

Collection time (00:00-23:59)

12:45 (24 HR)

Collection date and time (derived)

11 SEP 2020 12:45

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 19:25:38

Generated On: 11 Aug 2021 22:53:30

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:50	11 SEP 2020 12:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:25:38

Generated On: 11 Aug 2021 22:53:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

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

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

11 SEP 2020 13:43

PC Close Date & Time

11 SEP 2020 16:13

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

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 97.4 °F

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

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

PC Time Stamp	11 SEP 2020 17:32
PC Open Date & Time	11 SEP 2020 17:08
PC Close Date & Time	12 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

12 SEP 2020 13:48

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 13:01

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:30

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 19:07

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

15 SEP 2020 17:15

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:30

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 15:42

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 17:48

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

11 SEP 2020 13:43

PC Close Date & Time

11 SEP 2020 16:13

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

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

11 SEP 2020 17:34

PC Open Date & Time

11 SEP 2020 17:08

PC Close Date & Time

12 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:30

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

60

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 13:51

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:30

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 ☐

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

67

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

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

Yes ☒

No ☐

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

58

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 13:04

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT	DAY 4
Please record - PAIN AT INJECTION SITE. Please select one response below	None <input type="radio"/> Does not interfere with activity <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Please record - REDNESS AT INJECTION SITE (in mm)	74
Measure the largest size across any injection site redness with the ruler provided.	
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Please record - SWELLING/HARDNESS AT INJECTION SITE (in mm)	70
Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - UNDERARM GLAND SWELLING OR TENDERNESS. Please select one response below	None <input checked="" type="radio"/> 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	14 SEP 2020 19:08
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT	DAY 5
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 checked="" type="radio"/>
	No <input type="radio"/>
Please record - REDNESS AT INJECTION SITE (in mm)	55
Measure the largest size across any injection site redness with the ruler provided.	
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record - SWELLING/HARDNESS AT INJECTION SITE (in mm)	45
Measure the largest size across any injection site swelling/hardness with the ruler provided.	
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	15 SEP 2020 17:16
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT	DAY 6
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 checked="" type="radio"/>
	No <input type="radio"/>
Please record - REDNESS AT INJECTION SITE (in mm)	50
Measure the largest size across any injection site redness with the ruler provided.	
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record - SWELLING/HARDNESS AT INJECTION SITE (in mm)	35
Measure the largest size across any injection site swelling/hardness with the ruler provided.	
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	16 SEP 2020 15:35
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

42

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

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

17 SEP 2020 17:49

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

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 ☐

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

11 SEP 2020 13:43

PC Close Date & Time

11 SEP 2020 16:13

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

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 ☐

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 20:27
PC Open Date & Time	11 SEP 2020 17:08
PC Close Date & Time	12 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:30

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 ☒

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:30

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 13:53
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:30

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 ☒

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:30

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 13:05
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:30

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 ☒

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:30

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 19:09
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:30

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 ☒

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:30

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 17:17
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:30

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 ☒

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:30

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 15:36
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:30

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 17:50
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: Swelling_Day(8)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 8

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

Yes ☒

No ☐

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

40

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

PC Time stamp

18 SEP 2020 17:03

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: Swelling_Day(9)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT	DAY 9
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="checkbox"/>
	No <input checked="" type="radio"/>
PC Time stamp	20 SEP 2020 08:07
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp

18 SEP 2020 17:03

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3522664

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 SEP 2020 17:03
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3522664

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:25:38

Generated On: 11 Aug 2021 22:53:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK

US3522664

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:25:38

Generated On: 11 Aug 2021 22:53:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522664

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:25:38

Generated On: 11 Aug 2021 22:53:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

FLARE AT INJECTION SITE NOW
REDNESS 120MM BY 86MM.
SWELLING 56MM. NO PAIN. NO
DOC VISITS. MED OR MED
HISTORY CHANGES. NO COVID
EXPOSURE. DR ZERVOS ON
LINE DISCUSSING WITH
PATIENT.

US3522664

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:25:38

Generated On: 11 Aug 2021 22:53:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522664

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:25:38

Generated On: 11 Aug 2021 22:53:30

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 OCT 2020

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

Comments "NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK."

US3522664

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:25:38

Generated On: 11 Aug 2021 22:53:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522664

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:25:44

Generated On: 11 Aug 2021 22:53:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 19:25:44

Generated On: 11 Aug 2021 22:53:30

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 OCT 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 11:30
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 19:25:44

Generated On: 11 Aug 2021 22:53:30

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	

US3522664

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:25:44

Generated On: 11 Aug 2021 22:53:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 2020

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

US3522664

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 19:25:39

Generated On: 11 Aug 2021 22:53:30

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?

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?

US3522664

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:25:44

Generated On: 11 Aug 2021 22:53:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

11:42 (24 HR)

Collection date and time (derived)

12 OCT 2020 11:42

US3522664

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 19:25:39

Generated On: 11 Aug 2021 22:53:30

Collection date (dd MMM yyyy)			12 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:45	12 OCT 2020 11:45
Nasopharyngeal Swab 2	No		

US3522664

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:25:39

Generated On: 11 Aug 2021 22:53:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522664

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:25:38

Generated On: 11 Aug 2021 22:53:30

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

PER THE DISCRETION OF DR.
ZERVOS, PATIENT DID NOT
RECEIVE IP DURING VISIT 2
DUE TO ADVERSE REACTION
FROM THE 1ST INJECTION.
THEREFORE, NO EDIARY
ENTRY. NO COVID EXPOSURE.
HE WILL CONTINUE FOR VISIT

3

US3522664

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:25:38

Generated On: 11 Aug 2021 22:53:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522664

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:25:38

Generated On: 11 Aug 2021 22:53:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 OCT 2020

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

Comments
If Contact Not Made, please provide Comments
NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, OR COVID-19
EXPOSURE RISK

US3522664

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:25:38

Generated On: 11 Aug 2021 22:53:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522664

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:25:38

Generated On: 11 Aug 2021 22:53:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK.

US3522664

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:25:38

Generated On: 11 Aug 2021 22:53:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522664

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:25:44

Generated On: 11 Aug 2021 22:53:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3522664

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 19:25:44

Generated On: 11 Aug 2021 22:53:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 NOV 2020
Time of assessment (00:00-23:59)	11:10 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 11:10
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522664

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:25:44

Generated On: 11 Aug 2021 22:53:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 NOV 2020

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

US3522664

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:25:44

Generated On: 11 Aug 2021 22:53:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 NOV 2020

Collection time (00:00-23:59)

11:20 (24 HR)

Collection date and time (derived)

13 NOV 2020 11:20

US3522664

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:25:44

Generated On: 11 Aug 2021 22:53:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522664

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 00:11:45

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3522664

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

18 NOV 2020 18:21:48

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 09:26:54
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 09:33:47
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 09:44:54

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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	13 DEC 2020 09:17:23
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

21 DEC 2020 10:55:15

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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	27 DEC 2020 08:33:10
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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	03 JAN 2021 08:52:43
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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	10 JAN 2021 09:02:28
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

17 JAN 2021 06:02:32

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

24 JAN 2021 08:43:50

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 07:46:13

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

07 FEB 2021 09:05:10

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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 <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 FEB 2021 08:29:14
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 07:43:20

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

28 FEB 2021 16:08:02

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

07 MAR 2021 08:11:48

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

14 MAR 2021 08:54:14

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

21 MAR 2021 08:46:32

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

28 MAR 2021 12:42:52

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

06 APR 2021 18:48:04

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

11 APR 2021 08:12:04

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

18 APR 2021 10:02:05

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

25 APR 2021 08:12:50

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 MAY 2021 11:55:19
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 250

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

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

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

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

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

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

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 ☐

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 264

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

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

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

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

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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 ☐

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 418

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

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

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

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

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 460

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

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

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

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

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

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

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 ☐

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 516

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

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

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

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

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

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

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 ☐

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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 ☐

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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 ☐

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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 ☐

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 607

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

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

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

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

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 642

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

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

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

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

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

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

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 ☐

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

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 ☐

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 656

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

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

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

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

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

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

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 ☐

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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 ☐

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 698

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

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

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

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

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

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

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 ☐

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

Patient Cloud Open Date & Time	14 AUG 2022 00:01
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Patient Cloud Close Date & Time	18 AUG 2022 23:59
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US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 761

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

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

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

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

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

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

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 ☐

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 768

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

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

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

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

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

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

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 ☐

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

13 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3522664

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:53:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	28 FEB 2021 16:07:24

US3522664

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

REDNESS AFTER 1ST INJ WAS
FLAT WITH NO URTICARIA.
PATIENT STATES FLU VACCINE
09/25/202 AND NOT 08/15/2020 AS
PREVIOUSLY DOCUMENTED.
NO NEW AE'S ETC. SEE SOURCE

US3522664

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522664

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 JAN 2021

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

Comments
If Contact Not Made, please provide Comments
NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK.

US3522664

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522664

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 FEB 2021

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

Comments NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE

If Contact Not Made, please provide Comments

US3522664

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522664

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 15:42:09

Generated On: 11 Aug 2021 22:53:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 MAR 2021

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

Comments NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE

If Contact Not Made, please provide Comments

US3522664

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 15:42:09

Generated On: 11 Aug 2021 22:53:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522664

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 11:54:11

Generated On: 11 Aug 2021 22:53:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3522664

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 11:54:11

Generated On: 11 Aug 2021 22:53:30

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) _____

US3522664

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 11:54:11

Generated On: 11 Aug 2021 22:53:30

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.

US3522664

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 11:54:11

Generated On: 11 Aug 2021 22:53:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 APR 2021

Collection time (00:00-23:59)

10:25 (24 HR)

Collection date and time (derived)

2 APR 2021 10:25

US3522664

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 11:54:11

Generated On: 11 Aug 2021 22:53:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522664

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

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

US3522664

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3522664

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:53:30

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"/>

US3522664

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:53:30

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3522664

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

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

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

Folder OID	UNBLND_DECIDE
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US3522664

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 15:31:56

Generated On: 11 Aug 2021 22:53:30

Date of updated informed consent (<i>dd MMM yyyy</i>)	15 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	15 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3522664

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

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

US3522664

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 JAN 2021
Time of assessment (00:00-23:59)	10:58 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 10:58
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3522664

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 JAN 2021
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 11:40
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3522664

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

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 JAN 2021

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

US3522664

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

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 15 JAN 2021

What was the treatment time? (00:00-23:59) 11:05 (24 HR)

Treatment Date and Time (derived) 15 JAN 2021 11:05

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

What was the frequency of the study treatment dosing? ONCE

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

US3522664

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00-23:59)	11:00 (24 HR)
Collection date and time (derived)	15 JAN 2021 11:00

US3522664

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00 - 23:59)	11:00
Collection Date and Time (derived)	15 JAN 2021 11:00

US3522664

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

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522664

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Was Contact Attempted? Yes ☒ No ☐

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

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

Comments NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK

US3522664

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

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

US3522664

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

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

US3522664

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	10:19 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 10:19
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	69 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522664

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 FEB 2021

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

US3522664

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 FEB 2021

Collection time (00:00-23:59)

10:30 (24 HR)

Collection date and time (derived)

12 FEB 2021 10:30

US3522664

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 12:40:17

Generated On: 11 Aug 2021 22:53:30

AEID

Adverse event

RIGHT DELTOID MACULAR,
NON-URTICARIAL REDNESS AT
INJECTION SITE 120MM BY
86MM OBLONG

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

23 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 12:40:17

Generated On: 11 Aug 2021 22:53:30

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

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 12:40:17

Generated On: 11 Aug 2021 22:53:30

PARTICIPANT SENT AN EMAIL
TO REPORT A NEW
DEVELOPMENT ON DAY 13; I
CALLED HIM AT 11:21 AM
TODAY (24 SEP 2020) FOR
CLARIFICATION. HE REPORTS
THAT HIS ORIGINAL AES
RESOLVED BY DAY 8-9 AND BY
HIS SAFETY CALL DAY 7
(WHICH HAPPENED ON 21 SEP
2020, WHICH WAS DAY 11) HE
WAS FINE. BUT, ON 23 SEP 2020
HE HAD A SUDDEN FLARE AT
INJECTION SITE THAT HE
DESCRIBES AS A REDNESS OF
80 MM WITH SWELLING OF 62
MM AND WARM TO THE
TOUCH, ALSO TENDER WITH
PRESSURE. TODAY, REDNESS IS
STILL SPREAD OUT, BUT
SWELLING IS DOWN AND IT IS
NOT WARM TO TOUCH. HE DID
NOT TAKE ANY MEDICATIONS
25SEP2020 REDNESS OBLONG
SHAPE VERTICALLY DOWN
AND UP ARM 120MM LONG
WIDE 86MM. SWELLING 56MM
LONG. RELATES NOT PAINFUL.
SOME TENDERNESS. REPORTED
LATER THAT IT DID NOT LAST
PAST THE 26SEP2020.

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

US3522664

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 12:40:17

Generated On: 11 Aug 2021 22:53:30

AEID

Adverse event

SWELLING/INDURATION
(HARDNESS) AT INJECTION
SITE - MILD

Was this a medically-attended AE? Yes ☐
No ☒

Was this a Solicited Adverse Reaction? Yes ☒
No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐
No ☒

Start date (dd MMM yyyy) 15 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 18 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐
Unknown ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 12:40:17

Generated On: 11 Aug 2021 22:53:30

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

US3522664

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

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

Yes ☒

No ☐

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

US3522664

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3522664

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		25 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3522664

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3522664

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 05 Mar 2021 19:17:33

Generated On: 11 Aug 2021 22:53:30

Date of dosing discontinuation (dd MMM yyyy)	12 OCT 2020
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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
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US3522664

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:53:30

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

US3522664 (Prod: Henry Ford Health System)

US3522664

Form: Participant Creation

Generated On: 11 Aug 2021 22:53:30

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 00:02:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
	(b) (4)	
User entered 'US3522664'	RWS_ENDPOINT	11 Sep 2020 16:04:45
	ENDPOINT (b) (4)	
	(b) (4)	

US3522664

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:11:58

US3522664

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:15
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 16:04:46

US3522664

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:15
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Sep 2020 16:11:58

US3522664

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered 'SCRN'	System	11 Sep 2020 16:11:58

US3522664

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:30

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:18
User entered (b) (6) 1958'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 16:04:47

US3522664

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:30

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:18
User entered '62'	(b) (4), (b) (6)	11 Sep 2020 16:12:34

US3522664

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:30

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered 'YEARS'	System	11 Sep 2020 16:12:34

US3522664

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:30

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered '62'	System	11 Sep 2020 16:12:49

US3522664

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:30

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:18
User entered 'Male (M)'	(b) (4), (b) (6)	11 Sep 2020 16:12:34

US3522664

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:30

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:18
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	11 Sep 2020 16:12:34

US3522664

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:30

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:18
User entered 'I'	(b) (4), (b) (6)	11 Sep 2020 16:12:34

US3522664

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:30

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 19:59:18
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:12:34

US3522664

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:30

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:18
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:12:34

US3522664

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:30

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:18
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:12:34

US3522664

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:30

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:18
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:12:34

US3522664

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:18
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:12:34

US3522664

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:30

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:18
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:12:34

US3522664

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:30

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:18
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:12:34

US3522664

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:53:30

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:18
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:12:34

US3522664

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:24
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:12:49

US3522664

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered 'Sep 2020'	System	11 Sep 2020 16:12:49

US3522664

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered '2020'	System	11 Sep 2020 16:12:49

US3522664

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:30

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:24
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	11 Sep 2020 16:12:49

US3522664

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:12:49

US3522664

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:24
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:12:49

US3522664

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:30

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:24
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:12:49

US3522664

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:30

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:24
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:12:49

US3522664

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:30

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:24
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 16:04:46

US3522664

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:53:30

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered 'I'	System	11 Sep 2020 16:12:55

US3522664

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:12:55

US3522664

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:53:30

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:13:24

US3522664

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:47
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 16:14:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 16:14:40
Data point term sent to Coder	System	11 Sep 2020 16:13:42
User entered 'gerd'	(b) (4), (b) (6)	11 Sep 2020 16:13:36

US3522664

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:47
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:13:36

US3522664

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:47
User entered 'l'	(b) (4), (b) (6)	11 Sep 2020 16:13:36

US3522664

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:13:36

US3522664

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:47
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:13:36

US3522664

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:59:47
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:13:36

US3522664

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered empty.	System	11 Sep 2020 16:13:36

US3522664

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered empty.	System	11 Sep 2020 16:13:36

US3522664

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered empty.	System	11 Sep 2020 16:13:36

US3522664

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered empty.	System	11 Sep 2020 16:13:36

US3522664

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:04:32
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Botulinum toxin injection, LLT: Botulinum toxin injection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Mar 2021 15:47:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Mar 2021 15:47:43
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	09 Mar 2021 15:42:09
Data point term sent to Coder	System	09 Mar 2021 15:17:39
User entered 'Cosmetic Facial Botox (forehead and brow)'	Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 15:17:18

US3522664

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:04:32
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:42:09
User entered 'UN UNK 2016'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 15:17:18

US3522664

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:04:32
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:42:09
User entered '0'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 15:17:18

US3522664

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:04:32
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:42:09
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	09 Mar 2021 15:17:35
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	09 Mar 2021 15:17:18
User entered 'No (N)'	Yaman Ahmed (b) (4)	09 Mar 2021 15:17:18
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:04:32
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:42:09
User entered 'UN UNK 2019' reason for change:	(b) (4)	
Data Entry Error	Yaman Ahmed (b) (4)	09 Mar 2021 15:17:35
User entered empty.	(b) (4)	
	Yaman Ahmed (b) (4)	09 Mar 2021 15:17:18
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:04:32
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:42:09
User entered '0'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 15:17:18

US3522664

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered 'Jan 2016'	System	09 Mar 2021 15:17:18

US3522664

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered '2016'	System	09 Mar 2021 15:17:18

US3522664

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered 'Jan 2019'	System	09 Mar 2021 15:17:35
User entered empty.	System	09 Mar 2021 15:17:18

US3522664

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered '2019'	System	09 Mar 2021 15:17:35
User entered empty.	System	09 Mar 2021 15:17:18

US3522664

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:04:32
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Dermal filler injection, LLT: Dermal filler injection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Mar 2021 14:45:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Mar 2021 14:45:38
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	09 Mar 2021 15:42:09
Data point term sent to Coder	System	09 Mar 2021 15:19:41
User entered 'COSMETIC DERMAL FILLER (below orbs of the eyes and to creases around the mouth)' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 15:19:13
Data point term sent to Coder	System	09 Mar 2021 15:18:40
User entered 'Cosmetic Dermal Filler'	Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 15:18:24

US3522664

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:04:32
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:42:09
User entered 'UN UNK 2018'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 15:18:24

US3522664

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:04:32
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:42:09
User entered '0'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 15:18:24

US3522664

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:04:32
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:42:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 15:18:35
User entered 'No (N)' reason for change: Data Entry Error	System	09 Mar 2021 15:18:35
User entered 'No (N)' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	09 Mar 2021 15:18:35
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	09 Mar 2021 15:18:24
	Yaman Ahmed (b) (4)	09 Mar 2021 15:18:24
	(b) (4)	

US3522664

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:04:32
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:42:09
User entered 'UN UNK 2018' reason for change:	(b) (4)	
Data Entry Error	Yaman Ahmed (b) (4)	09 Mar 2021 15:18:35
User entered empty.	(b) (4)	
	Yaman Ahmed (b) (4)	09 Mar 2021 15:18:24
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:04:32
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:42:09
User entered '0'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 15:18:24

US3522664

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered 'Jan 2018'	System	09 Mar 2021 15:18:24

US3522664

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered '2018'	System	09 Mar 2021 15:18:24

US3522664

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered 'Jan 2018'	System	09 Mar 2021 15:18:35
User entered empty.	System	09 Mar 2021 15:18:24

US3522664

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered '2018'	System	09 Mar 2021 15:18:35
User entered empty.	System	09 Mar 2021 15:18:24

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:25:43

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:00:01
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:25:43

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:01
User entered '12:23'	(b) (4), (b) (6)	11 Sep 2020 16:25:43

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered '11 Sep 2020 12:23'	System	11 Sep 2020 16:25:43

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:01
User entered '70' in	(b) (4), (b) (6)	11 Sep 2020 16:25:43
DataPoint set to visible.	System	11 Sep 2020 16:12:55

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:01
User entered '177' lb	(b) (4), (b) (6)	11 Sep 2020 16:25:43
DataPoint set to visible.	System	11 Sep 2020 16:12:55

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered '25.44996'	System	11 Sep 2020 16:25:43
DataPoint set to visible.	System	11 Sep 2020 16:12:55

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered 'kg/m2'	System	11 Sep 2020 16:25:43
DataPoint set to visible.	System	11 Sep 2020 16:12:55

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:00:01
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 16:25:43

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:01
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:25:43

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:00:01
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:25:43

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:00:01
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 16:25:43

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered 'bpm'	System	11 Sep 2020 16:25:43

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:01
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 16:25:43

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered 'breaths/min'	System	11 Sep 2020 16:25:43

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:01
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 16:25:43

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered 'mmHg'	System	11 Sep 2020 16:25:43

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:01
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 16:25:43

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User entered 'mmHg'	System	11 Sep 2020 16:25:43

US3522664

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31

US3522664

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 17:05:52
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:05:27

US3522664

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:00:06
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 17:05:52
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:05:27

US3522664

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:22:03

US3522664

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:22:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

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)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:22:03

US3522664

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

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)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:22:03

US3522664

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:22:03

US3522664

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

[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)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:22:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

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)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:22:03

US3522664

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

[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)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:22:03

US3522664

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

[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)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:22:03

US3522664

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

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)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:22:03

US3522664

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

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)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:22:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:22:03

US3522664

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:22:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:22:03

US3522664

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:22:03

US3522664

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

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)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:22:03

US3522664

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

[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)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:22:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

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)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 16:22:03

US3522664

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered 'l'	(b) (4), (b) (6)	11 Sep 2020 16:22:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:22:03

US3522664

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:53:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:14
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:22:03

US3522664

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:14:19

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:18
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:14:19

US3522664

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:18
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Sep 2020 16:14:19

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered 'VISIT1'	System	11 Sep 2020 16:14:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:24
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 16:19:23

US3522664

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:24
User entered '113425'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 16:19:23

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:24
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 16:19:23

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:24
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:14:44

US3522664

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:24
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:14:44

US3522664

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:30

[Severe obesity \(body mass index > or = 40kg/m2\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:24
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:14:44

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:24
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:14:44

US3522664

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:30

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:24
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:14:44

US3522664

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:24
User entered 'No (N)'	Kristin Eis (b) (4)	24 Sep 2020 18:09:13
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 06:11:00
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:10:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 16:24:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:24:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered '12:23'	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered '11 Sep 2020 12:23'	System	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered '98.4' F	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered 'Other (Other)'	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered 'temporal'	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered '71'	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered 'bpm'	System	11 Sep 2020 16:24:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered '20'	(b) (4), (b) (6)	11 Sep 2020 16:24:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered 'breaths/min'	System	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Sep 2020 16:26:10
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	11 Sep 2020 16:26:10
User entered '143' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 16:26:10
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Sep 2020 16:24:10
User entered '165'	(b) (4), (b) (6)	11 Sep 2020 16:24:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered 'mmHg'	System	11 Sep 2020 16:24:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Sep 2020 16:26:10
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	11 Sep 2020 16:26:10
User entered '90' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 16:26:10
User opened query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Sep 2020 16:24:10
User entered '104'	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered 'mmHg'	System	11 Sep 2020 16:24:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 16:24:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:27:38
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:24:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:27:38
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:24:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered '13:53' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:27:38
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:24:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered '11 Sep 2020 13:53'	System	11 Sep 2020 18:27:38
User entered empty.	System	11 Sep 2020 16:24:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered '97.4' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:27:38
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:27:38
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered 'TEMPORAL' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:27:38
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:27:38
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered 'bpm'	System	11 Sep 2020 18:27:38
User entered empty.	System	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered '12' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:27:38
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered 'breaths/min'	System	11 Sep 2020 18:27:38
User entered empty.	System	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered '144' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:27:38
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered 'mmHg'	System	11 Sep 2020 18:27:38
User entered empty.	System	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:28
User entered '94' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 18:27:38
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered 'mmHg'	System	11 Sep 2020 18:27:38
User entered empty.	System	11 Sep 2020 16:24:10

US3522664

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:33
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:27:56

US3522664

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:00:33
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:27:56

US3522664

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:24:57

US3522664

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:40
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:24:57

US3522664

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:40
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:24:57

US3522664

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 17:24:57

US3522664

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:40
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 17:24:57

US3522664

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:40
User entered '13:23'	(b) (4), (b) (6)	11 Sep 2020 17:24:57

US3522664

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered '11 Sep 2020 13:23'	System	11 Sep 2020 17:24:57

US3522664

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:40
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	11 Sep 2020 17:24:57

US3522664

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:00:40
User entered 'ONCE'	System	11 Sep 2020 17:24:57

US3522664

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 17:24:57

US3522664

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:05:00

US3522664

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:00:47
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 17:05:00

US3522664

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:47
User entered '12:45'	(b) (4), (b) (6)	11 Sep 2020 17:05:00

US3522664

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered '11 Sep 2020 12:45'	System	11 Sep 2020 17:05:00

US3522664

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:53:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:00:52
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 17:05:11

US3522664

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Sep 2020 17:05:11

US3522664

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 17:05:11

US3522664

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:52
User entered '12:50'	(b) (4), (b) (6)	11 Sep 2020 17:05:11

US3522664

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered '11 Sep 2020 12:50'	System	11 Sep 2020 17:05:11

US3522664

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Sep 2020 17:05:11

US3522664

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:52
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 17:05:11

US3522664

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:00:52
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 17:05:11

US3522664

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered empty.	System	11 Sep 2020 17:05:11

US3522664

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:00:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 16:28:52

US3522664

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered '1'	System	11 Sep 2020 16:28:52

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '11 Sep 2020 13:43'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '11 Sep 2020 16:13'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-11T17:31:42', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e6271876-54e7-4a8c-bf06-780fe41e88d7' User entered 'Yes (Y)'	System	11 Sep 2020 21:32:20
	System	11 Sep 2020 21:32:20

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-11T17:31:52', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e6271876-54e7-4a8c-bf06-780fe41e88d7' User entered '97.4'	System	11 Sep 2020 21:32:20
	System	11 Sep 2020 21:32:20

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-11T17:31:57', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e6271876-54e7-4a8c-bf06-780fe41e88d7'	System	11 Sep 2020 21:32:20
User entered 'No (N)'	System	11 Sep 2020 21:32:20

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-11T17:32:13', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e6271876-54e7-4a8c-bf06-780fe41e88d7'	System	11 Sep 2020 21:32:20
User entered '11 Sep 2020 17:32'	System	11 Sep 2020 21:32:20

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '11 Sep 2020 17:08'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 2'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-12T13:48:26', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'a2fda546-fa74-4730-9d8f-07f94cfd14f8'	System	12 Sep 2020 17:48:52
User entered 'Yes (Y)'	System	12 Sep 2020 17:48:52

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-12T13:48:33', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'a2fda546-fa74-4730-9d8f-07f94cfd14f8' User entered '98.6'	System	12 Sep 2020 17:48:52
	System	12 Sep 2020 17:48:52

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-12T13:48:37', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'a2fda546-fa74-4730-9d8f-07f94cfd14f8'	System	12 Sep 2020 17:48:52
User entered 'No (N)'	System	12 Sep 2020 17:48:52

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-12T13:48:49', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'a2fda546-fa74-4730-9d8f-07f94cfd14f8'	System	12 Sep 2020 17:48:52
User entered '12 Sep 2020 13:48'	System	12 Sep 2020 17:48:52

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 3'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:01:36', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '5e338141-0db6-4984-8c01-f6468f757659' User entered 'Yes (Y)'	System	13 Sep 2020 17:02:43
	System	13 Sep 2020 17:02:43

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:01:46', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '5e338141-0db6-4984-8c01-f6468f757659' User entered '98.1'	System	13 Sep 2020 17:02:43
	System	13 Sep 2020 17:02:43

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:01:50', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '5e338141-0db6-4984-8c01-f6468f757659' User entered 'No (N)'	System	13 Sep 2020 17:02:43
	System	13 Sep 2020 17:02:43

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:01:56', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '5e338141-0db6-4984-8c01-f6468f757659' User entered '13 Sep 2020 13:01'	System	13 Sep 2020 17:02:43
	System	13 Sep 2020 17:02:43

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 4'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:07:11', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '92998abb-748c-45e1-be2b-bb73ad96d3dd' User entered 'Yes (Y)'	System	14 Sep 2020 23:07:37
	System	14 Sep 2020 23:07:37

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:07:22', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '92998abb-748c-45e1-be2b-bb73ad96d3dd' User entered '98.3'	System	14 Sep 2020 23:07:37
	System	14 Sep 2020 23:07:37

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:07:27', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '92998abb-748c-45e1-be2b-bb73ad96d3dd' User entered 'No (N)'	System	14 Sep 2020 23:07:37
	System	14 Sep 2020 23:07:37

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:07:32', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '92998abb-748c-45e1-be2b-bb73ad96d3dd' User entered '14 Sep 2020 19:07'	System	14 Sep 2020 23:07:37
	System	14 Sep 2020 23:07:37

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 5'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:15:10', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '0d3cd09c-da49-42f0-b34c-3acd9c76a400' User entered 'Yes (Y)'	System	15 Sep 2020 21:15:43
	System	15 Sep 2020 21:15:43

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:15:30', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '0d3cd09c-da49-42f0-b34c-3acd9c76a400' User entered '98.0'	System	15 Sep 2020 21:15:43
	System	15 Sep 2020 21:15:43

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:15:34', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '0d3cd09c-da49-42f0-b34c-3acd9c76a400' User entered 'No (N)'	System	15 Sep 2020 21:15:43
	System	15 Sep 2020 21:15:43

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:15:40', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '0d3cd09c-da49-42f0-b34c-3acd9c76a400' User entered '15 Sep 2020 17:15'	System	15 Sep 2020 21:15:43
	System	15 Sep 2020 21:15:43

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 6'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:41:48', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '2ca23f0c-94f9-47bc-8a47-6281cc7b006d' User entered 'Yes (Y)'	System	16 Sep 2020 19:42:05
	System	16 Sep 2020 19:42:05

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:41:53', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '2ca23f0c-94f9-47bc-8a47-6281cc7b006d' User entered '97.8'	System	16 Sep 2020 19:42:05
	System	16 Sep 2020 19:42:05

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:41:56', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '2ca23f0c-94f9-47bc-8a47-6281cc7b006d' User entered 'No (N)'	System	16 Sep 2020 19:42:05
	System	16 Sep 2020 19:42:05

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:42:01', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '2ca23f0c-94f9-47bc-8a47-6281cc7b006d' User entered '16 Sep 2020 15:42'	System	16 Sep 2020 19:42:05
	System	16 Sep 2020 19:42:05

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 7'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-17T17:48:24', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'd2b7492f-b45c-4a19-b2e5-9a775f24ff89' User entered 'Yes (Y)'	System	17 Sep 2020 21:48:39
	System	17 Sep 2020 21:48:39

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-17T17:48:31', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'd2b7492f-b45c-4a19-b2e5-9a775f24ff89' User entered '97.9'	System	17 Sep 2020 21:48:39
	System	17 Sep 2020 21:48:39

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-17T17:48:34', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'd2b7492f-b45c-4a19-b2e5-9a775f24ff89'	System	17 Sep 2020 21:48:39
User entered 'No (N)'	System	17 Sep 2020 21:48:39

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-17T17:48:37', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'd2b7492f-b45c-4a19-b2e5-9a775f24ff89' User entered '17 Sep 2020 17:48'	System	17 Sep 2020 21:48:39
	System	17 Sep 2020 21:48:39

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '11 Sep 2020 13:43'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '11 Sep 2020 16:13'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-11T17:32:46', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '74b6a307-e1d0-4b1d-9af9-79fa6ec88391'	System	11 Sep 2020 21:34:20
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 21:34:20

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-11T17:33:25', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '74b6a307-e1d0-4b1d-9af9-79fa6ec88391' User entered 'No (N)'	System	11 Sep 2020 21:34:20
	System	11 Sep 2020 21:34:20

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-11T17:33:32', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '74b6a307-e1d0-4b1d-9af9-79fa6ec88391' User entered 'No (N)'	System	11 Sep 2020 21:34:20
	System	11 Sep 2020 21:34:20

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-11T17:34:08', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '74b6a307-e1d0-4b1d-9af9-79fa6ec88391' User entered 'None (1)'	System	11 Sep 2020 21:34:20
	System	11 Sep 2020 21:34:20

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-11T17:34:17', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '74b6a307-e1d0-4b1d-9af9-79fa6ec88391' User entered '11 Sep 2020 17:34'	System	11 Sep 2020 21:34:20
	System	11 Sep 2020 21:34:20

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '11 Sep 2020 17:08'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 2'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-12T13:50:09', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '2a5ae78f-85cd-4aef-86a3-9e152464857c'	System	12 Sep 2020 17:51:36
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 17:51:36

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-12T13:50:16', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '2a5ae78f-85cd-4aef-86a3-9e152464857c' User entered 'No (N)'	System	12 Sep 2020 17:51:36
	System	12 Sep 2020 17:51:36

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-12T13:50:20', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '2a5ae78f-85cd-4aef-86a3-9e152464857c' User entered 'Yes (Y)'	System	12 Sep 2020 17:51:36
	System	12 Sep 2020 17:51:36

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-12T13:51:05', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '2a5ae78f-85cd-4aef-86a3-9e152464857c' User entered '60'	System	12 Sep 2020 17:51:36
	System	12 Sep 2020 17:51:36

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-12T13:51:20', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '2a5ae78f-85cd-4aef-86a3-9e152464857c'	System	12 Sep 2020 17:51:36
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 17:51:36

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-12T13:51:32', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '2a5ae78f-85cd-4aef-86a3-9e152464857c' User entered '12 Sep 2020 13:51'	System	12 Sep 2020 17:51:36
	System	12 Sep 2020 17:51:36

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 3'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:02:14', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '763cbd04-864b-4daa-a662-4cad2aa1a1c9'	System	13 Sep 2020 17:04:55
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 17:04:55

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:04:12', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '763cbd04-864b-4daa-a662-4cad2aa1a1c9'	System	13 Sep 2020 17:04:55
User entered 'Yes (Y)'	System	13 Sep 2020 17:04:55

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:04:08', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '763cbd04-864b-4daa-a662-4cad2aa1a1c9' User entered '67'	System	13 Sep 2020 17:04:55
	System	13 Sep 2020 17:04:55

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:04:07', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '763cbd04-864b-4daa-a662-4cad2aa1a1c9'	System	13 Sep 2020 17:04:55
User entered 'Yes (Y)'	System	13 Sep 2020 17:04:55

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:04:20', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '763cbd04-864b-4daa-a662-4cad2aa1a1c9' User entered '58'	System	13 Sep 2020 17:04:55
	System	13 Sep 2020 17:04:55

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:04:34', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '763cbd04-864b-4daa-a662-4cad2aa1a1c9'	System	13 Sep 2020 17:04:55
User entered 'None (1)'	System	13 Sep 2020 17:04:55

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:04:54', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '763cbd04-864b-4daa-a662-4cad2aa1a1c9' User entered '13 Sep 2020 13:04'	System	13 Sep 2020 17:04:55
	System	13 Sep 2020 17:04:55

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 4'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:07:42', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e95097b0-8efc-4568-b2c5-7589af89a3b7'	System	14 Sep 2020 23:08:48
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 23:08:48

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:07:46', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e95097b0-8efc-4568-b2c5-7589af89a3b7' User entered 'Yes (Y)'	System	14 Sep 2020 23:08:48
	System	14 Sep 2020 23:08:48

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:07:59', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e95097b0-8efc-4568-b2c5-7589af89a3b7' User entered '74'	System	14 Sep 2020 23:08:48
	System	14 Sep 2020 23:08:48

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:08:05', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e95097b0-8efc-4568-b2c5-7589af89a3b7' User entered 'Yes (Y)'	System	14 Sep 2020 23:08:48
	System	14 Sep 2020 23:08:48

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:08:15', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e95097b0-8efc-4568-b2c5-7589af89a3b7' User entered '70'	System	14 Sep 2020 23:08:48
	System	14 Sep 2020 23:08:48

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:08:38', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e95097b0-8efc-4568-b2c5-7589af89a3b7' User entered 'None (1)'	System	14 Sep 2020 23:08:48
	System	14 Sep 2020 23:08:48

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:08:43', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e95097b0-8efc-4568-b2c5-7589af89a3b7' User entered '14 Sep 2020 19:08'	System	14 Sep 2020 23:08:48
	System	14 Sep 2020 23:08:48

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 5'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:16:07', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'b7b359e8-2a3c-40c9-a931-e93cc016436a' User entered 'None (1)'	System	15 Sep 2020 21:16:38
	System	15 Sep 2020 21:16:38

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:16:11', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'b7b359e8-2a3c-40c9-a931-e93cc016436a' User entered 'Yes (Y)'	System	15 Sep 2020 21:16:38
	System	15 Sep 2020 21:16:38

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:16:16', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'b7b359e8-2a3c-40c9-a931-e93cc016436a' User entered '55'	System	15 Sep 2020 21:16:38
	System	15 Sep 2020 21:16:38

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:16:20', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'b7b359e8-2a3c-40c9-a931-e93cc016436a' User entered 'Yes (Y)'	System	15 Sep 2020 21:16:38
	System	15 Sep 2020 21:16:38

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:16:23', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'b7b359e8-2a3c-40c9-a931-e93cc016436a' User entered '45'	System	15 Sep 2020 21:16:38
	System	15 Sep 2020 21:16:38

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:16:30', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'b7b359e8-2a3c-40c9-a931-e93cc016436a' User entered 'None (1)'	System	15 Sep 2020 21:16:38
	System	15 Sep 2020 21:16:38

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:16:36', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'b7b359e8-2a3c-40c9-a931-e93cc016436a' User entered '15 Sep 2020 17:16'	System	15 Sep 2020 21:16:38
	System	15 Sep 2020 21:16:38

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 6'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:34:55', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'c86eabed-4c62-40d7-ad06-db2891499b83'	System	16 Sep 2020 19:35:40
User entered 'None (1)'	System	16 Sep 2020 19:35:40

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:35:02', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'c86eabed-4c62-40d7-ad06-db2891499b83' User entered 'Yes (Y)'	System	16 Sep 2020 19:35:40
	System	16 Sep 2020 19:35:40

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:35:07', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'c86eabed-4c62-40d7-ad06-db2891499b83' User entered '50'	System	16 Sep 2020 19:35:40
	System	16 Sep 2020 19:35:40

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:35:13', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'c86eabed-4c62-40d7-ad06-db2891499b83' User entered 'Yes (Y)'	System	16 Sep 2020 19:35:40
	System	16 Sep 2020 19:35:40

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:35:17', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'c86eabed-4c62-40d7-ad06-db2891499b83' User entered '35'	System	16 Sep 2020 19:35:40
	System	16 Sep 2020 19:35:40

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:35:21', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'c86eabed-4c62-40d7-ad06-db2891499b83' User entered 'None (1)'	System	16 Sep 2020 19:35:40
	System	16 Sep 2020 19:35:40

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:35:38', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'c86eabed-4c62-40d7-ad06-db2891499b83' User entered '16 Sep 2020 15:35'	System	16 Sep 2020 19:35:40
	System	16 Sep 2020 19:35:40

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 7'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-17T17:48:42', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'aa693bca-5338-43b9-86ec-7a1ef6e1c120'	System	17 Sep 2020 21:49:12
User entered 'None (1)'	System	17 Sep 2020 21:49:12

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-17T17:48:46', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'aa693bca-5338-43b9-86ec-7a1ef6e1c120' User entered 'No (N)'	System	17 Sep 2020 21:49:12
	System	17 Sep 2020 21:49:12

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-17T17:48:48', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'aa693bca-5338-43b9-86ec-7a1ef6e1c120' User entered 'Yes (Y)'	System	17 Sep 2020 21:49:12
	System	17 Sep 2020 21:49:12

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-17T17:48:54', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'aa693bca-5338-43b9-86ec-7a1ef6e1c120' User entered '42'	System	17 Sep 2020 21:49:12
	System	17 Sep 2020 21:49:12

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-17T17:49:04', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'aa693bca-5338-43b9-86ec-7a1ef6e1c120'	System	17 Sep 2020 21:49:12
User entered 'None (1)'	System	17 Sep 2020 21:49:12

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-17T17:49:09', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'aa693bca-5338-43b9-86ec-7a1ef6e1c120'	System	17 Sep 2020 21:49:12
User entered '17 Sep 2020 17:49'	System	17 Sep 2020 21:49:12

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '11 Sep 2020 13:43'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '11 Sep 2020 16:13'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-11T20:24:48', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '5d023ae3-30f9-4a36-95d1-f345344bf8b7' User entered 'None (0)'	System	12 Sep 2020 00:27:07
	System	12 Sep 2020 00:27:07

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-11T20:24:56', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '5d023ae3-30f9-4a36-95d1-f345344bf8b7' User entered 'None (0)'	System	12 Sep 2020 00:27:07
	System	12 Sep 2020 00:27:07

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-11T20:25:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '5d023ae3-30f9-4a36-95d1-f345344bf8b7' User entered 'None (0)'	System	12 Sep 2020 00:27:07
	System	12 Sep 2020 00:27:07

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-11T20:25:04', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '5d023ae3-30f9-4a36-95d1-f345344bf8b7' User entered 'None (0)'	System	12 Sep 2020 00:27:07
	System	12 Sep 2020 00:27:07

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-11T20:25:07', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '5d023ae3-30f9-4a36-95d1-f345344bf8b7' User entered 'None (0)'	System	12 Sep 2020 00:27:07
	System	12 Sep 2020 00:27:07

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-11T20:25:11', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '5d023ae3-30f9-4a36-95d1-f345344bf8b7' User entered 'None (0)'	System	12 Sep 2020 00:27:07
	System	12 Sep 2020 00:27:07

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-11T20:25:23', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '5d023ae3-30f9-4a36-95d1-f345344bf8b7' User entered 'No (N)'	System	12 Sep 2020 00:27:07
	System	12 Sep 2020 00:27:07

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-11T20:27:04', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '5d023ae3-30f9-4a36-95d1-f345344bf8b7' User entered '11 Sep 2020 20:27'	System	12 Sep 2020 00:27:07
	System	12 Sep 2020 00:27:07

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '11 Sep 2020 17:08'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 2'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-12T13:52:25', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '231e6fe7-0c12-4297-8cca-c45199be2edc' User entered 'None (0)'	System	12 Sep 2020 17:53:47
	System	12 Sep 2020 17:53:47

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-12T13:52:47', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '231e6fe7-0c12-4297-8cca-c45199be2edc' User entered 'None (0)'	System	12 Sep 2020 17:53:47
	System	12 Sep 2020 17:53:47

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-12T13:53:04', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '231e6fe7-0c12-4297-8cca-c45199be2edc' User entered 'None (0)'	System	12 Sep 2020 17:53:47
	System	12 Sep 2020 17:53:47

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-12T13:53:11', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '231e6fe7-0c12-4297-8cca-c45199be2edc' User entered 'None (0)'	System	12 Sep 2020 17:53:47
	System	12 Sep 2020 17:53:47

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-12T13:53:27', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '231e6fe7-0c12-4297-8cca-c45199be2edc' User entered 'None (0)'	System	12 Sep 2020 17:53:47
	System	12 Sep 2020 17:53:47

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-12T13:53:30', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '231e6fe7-0c12-4297-8cca-c45199be2edc' User entered 'None (0)'	System	12 Sep 2020 17:53:47
	System	12 Sep 2020 17:53:47

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-12T13:53:35', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '231e6fe7-0c12-4297-8cca-c45199be2edc' User entered 'No (N)'	System	12 Sep 2020 17:53:47
	System	12 Sep 2020 17:53:47

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-12T13:53:41', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '231e6fe7-0c12-4297-8cca-c45199be2edc' User entered '12 Sep 2020 13:53'	System	12 Sep 2020 17:53:47
	System	12 Sep 2020 17:53:47

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 3'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:05:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '40e4623a-11d7-4a87-b045-2a2d9bf06f26' User entered 'None (0)'	System	13 Sep 2020 17:06:01
	System	13 Sep 2020 17:06:01

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:05:06', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '40e4623a-11d7-4a87-b045-2a2d9bf06f26' User entered 'None (0)'	System	13 Sep 2020 17:06:01
	System	13 Sep 2020 17:06:01

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:05:11', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '40e4623a-11d7-4a87-b045-2a2d9bf06f26' User entered 'None (0)'	System	13 Sep 2020 17:06:01
	System	13 Sep 2020 17:06:01

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:05:16', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '40e4623a-11d7-4a87-b045-2a2d9bf06f26' User entered 'None (0)'	System	13 Sep 2020 17:06:01
	System	13 Sep 2020 17:06:01

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:05:19', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '40e4623a-11d7-4a87-b045-2a2d9bf06f26' User entered 'None (0)'	System	13 Sep 2020 17:06:01
	System	13 Sep 2020 17:06:01

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:05:36', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '40e4623a-11d7-4a87-b045-2a2d9bf06f26'	System	13 Sep 2020 17:06:01
User entered 'No interference with activity (1)'	System	13 Sep 2020 17:06:01

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:05:49', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '40e4623a-11d7-4a87-b045-2a2d9bf06f26' User entered 'No (N)'	System	13 Sep 2020 17:06:01
	System	13 Sep 2020 17:06:01

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-13T13:05:59', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '40e4623a-11d7-4a87-b045-2a2d9bf06f26' User entered '13 Sep 2020 13:05'	System	13 Sep 2020 17:06:01
	System	13 Sep 2020 17:06:01

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 4'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:08:49', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e5daa99d-d296-45ca-9a9d-5247e0e922a3' User entered 'None (0)'	System	14 Sep 2020 23:09:43
	System	14 Sep 2020 23:09:43

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:08:52', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e5daa99d-d296-45ca-9a9d-5247e0e922a3' User entered 'None (0)'	System	14 Sep 2020 23:09:43
	System	14 Sep 2020 23:09:43

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:08:54', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e5daa99d-d296-45ca-9a9d-5247e0e922a3' User entered 'None (0)'	System	14 Sep 2020 23:09:43
	System	14 Sep 2020 23:09:43

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:08:56', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e5daa99d-d296-45ca-9a9d-5247e0e922a3' User entered 'None (0)'	System	14 Sep 2020 23:09:43
	System	14 Sep 2020 23:09:43

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:08:59', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e5daa99d-d296-45ca-9a9d-5247e0e922a3' User entered 'None (0)'	System	14 Sep 2020 23:09:43
	System	14 Sep 2020 23:09:43

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:09:21', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e5daa99d-d296-45ca-9a9d-5247e0e922a3' User entered 'None (0)'	System	14 Sep 2020 23:09:43
	System	14 Sep 2020 23:09:43

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:09:32', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e5daa99d-d296-45ca-9a9d-5247e0e922a3' User entered 'No (N)'	System	14 Sep 2020 23:09:43
	System	14 Sep 2020 23:09:43

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-14T19:09:37', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e5daa99d-d296-45ca-9a9d-5247e0e922a3' User entered '14 Sep 2020 19:09'	System	14 Sep 2020 23:09:43
	System	14 Sep 2020 23:09:43

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 5'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:16:42', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'c173a7b2-f42d-4501-b356-67f734ae1edf' User entered 'None (0)'	System	15 Sep 2020 21:17:06
	System	15 Sep 2020 21:17:06

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:16:44', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'c173a7b2-f42d-4501-b356-67f734ae1edf' User entered 'None (0)'	System	15 Sep 2020 21:17:06
	System	15 Sep 2020 21:17:06

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:16:47', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'c173a7b2-f42d-4501-b356-67f734ae1edf' User entered 'None (0)'	System	15 Sep 2020 21:17:06
	System	15 Sep 2020 21:17:06

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:16:49', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'c173a7b2-f42d-4501-b356-67f734ae1edf' User entered 'None (0)'	System	15 Sep 2020 21:17:06
	System	15 Sep 2020 21:17:06

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:16:51', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'c173a7b2-f42d-4501-b356-67f734ae1edf' User entered 'None (0)'	System	15 Sep 2020 21:17:06
	System	15 Sep 2020 21:17:06

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:16:54', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'c173a7b2-f42d-4501-b356-67f734ae1edf' User entered 'None (0)'	System	15 Sep 2020 21:17:06
	System	15 Sep 2020 21:17:06

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:16:57', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'c173a7b2-f42d-4501-b356-67f734ae1edf' User entered 'No (N)'	System	15 Sep 2020 21:17:06
	System	15 Sep 2020 21:17:06

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-15T17:17:01', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'c173a7b2-f42d-4501-b356-67f734ae1edf' User entered '15 Sep 2020 17:17'	System	15 Sep 2020 21:17:06
	System	15 Sep 2020 21:17:06

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 6'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:35:45', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '0479f2c5-2aad-47ca-9e99-0a77178fea01' User entered 'None (0)'	System	16 Sep 2020 19:36:16
	System	16 Sep 2020 19:36:16

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:35:49', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '0479f2c5-2aad-47ca-9e99-0a77178fea01' User entered 'None (0)'	System	16 Sep 2020 19:36:16
	System	16 Sep 2020 19:36:16

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:35:52', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '0479f2c5-2aad-47ca-9e99-0a77178fea01' User entered 'None (0)'	System	16 Sep 2020 19:36:16
	System	16 Sep 2020 19:36:16

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:35:56', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '0479f2c5-2aad-47ca-9e99-0a77178fea01' User entered 'None (0)'	System	16 Sep 2020 19:36:16
	System	16 Sep 2020 19:36:16

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:35:59', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '0479f2c5-2aad-47ca-9e99-0a77178fea01' User entered 'None (0)'	System	16 Sep 2020 19:36:16
	System	16 Sep 2020 19:36:16

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:36:03', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '0479f2c5-2aad-47ca-9e99-0a77178fea01' User entered 'None (0)'	System	16 Sep 2020 19:36:16
	System	16 Sep 2020 19:36:16

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:36:08', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '0479f2c5-2aad-47ca-9e99-0a77178fea01' User entered 'No (N)'	System	16 Sep 2020 19:36:16
	System	16 Sep 2020 19:36:16

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-16T15:36:14', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '0479f2c5-2aad-47ca-9e99-0a77178fea01' User entered '16 Sep 2020 15:36'	System	16 Sep 2020 19:36:16
	System	16 Sep 2020 19:36:16

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 7'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-17T17:49:57', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'cb0a645c-74db-413e-a8da-4d4d78720f25'	System	17 Sep 2020 21:50:30
User entered 'No interference with activity (1)'	System	17 Sep 2020 21:50:30

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-17T17:49:59', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'cb0a645c-74db-413e-a8da-4d4d78720f25' User entered 'None (0)'	System	17 Sep 2020 21:50:30
	System	17 Sep 2020 21:50:30

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-17T17:50:01', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'cb0a645c-74db-413e-a8da-4d4d78720f25' User entered 'None (0)'	System	17 Sep 2020 21:50:30
	System	17 Sep 2020 21:50:30

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-17T17:50:03', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'cb0a645c-74db-413e-a8da-4d4d78720f25' User entered 'None (0)'	System	17 Sep 2020 21:50:30
	System	17 Sep 2020 21:50:30

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-17T17:50:07', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'cb0a645c-74db-413e-a8da-4d4d78720f25' User entered 'None (0)'	System	17 Sep 2020 21:50:30
	System	17 Sep 2020 21:50:30

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-17T17:50:09', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'cb0a645c-74db-413e-a8da-4d4d78720f25' User entered 'None (0)'	System	17 Sep 2020 21:50:30
	System	17 Sep 2020 21:50:30

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-17T17:50:20', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'cb0a645c-74db-413e-a8da-4d4d78720f25'	System	17 Sep 2020 21:50:30
User entered 'No (N)'	System	17 Sep 2020 21:50:30

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-17T17:50:27', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'cb0a645c-74db-413e-a8da-4d4d78720f25' User entered '17 Sep 2020 17:50'	System	17 Sep 2020 21:50:30
	System	17 Sep 2020 21:50:30

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Diary Dose 1 (1)

Form: Swelling_Day(8)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	16 Sep 2020 19:35:40
User entered 'Day 8'	System	16 Sep 2020 19:35:40

US3522664

Folder: Diary Dose 1 (1)

Form: Swelling_Day(8)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-18T17:03:13', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '5a34d02a-7fb3-49d1-8b46-acd8c22238be' User entered 'Yes (Y)'	System	18 Sep 2020 21:03:27
	System	18 Sep 2020 21:03:27

US3522664

Folder: Diary Dose 1 (1)

Form: Swelling_Day(8)

Generated On: 11 Aug 2021 22:53:30

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-18T17:03:19', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '5a34d02a-7fb3-49d1-8b46-acd8c22238be' User entered '40'	System	18 Sep 2020 21:03:27
	System	18 Sep 2020 21:03:27

US3522664

Folder: Diary Dose 1 (1)

Form: Swelling_Day(8)

Generated On: 11 Aug 2021 22:53:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-18T17:03:23', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '5a34d02a-7fb3-49d1-8b46-acd8c22238be' User entered '18 Sep 2020 17:03'	System	18 Sep 2020 21:03:27
	System	18 Sep 2020 21:03:27

US3522664

Folder: Diary Dose 1 (1)

Form: Swelling_Day(8)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 19:35:40

US3522664

Folder: Diary Dose 1 (1)

Form: Swelling_Day(8)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 19:35:40

US3522664

Folder: Diary Dose 1 (1)

Form: Swelling_Day(9)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	17 Sep 2020 21:49:12
User entered 'Day 9'	System	17 Sep 2020 21:49:12

US3522664

Folder: Diary Dose 1 (1)

Form: Swelling_Day(9)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-20T08:07:01', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '14579be4-f4eb-4300-9425-e897868bc5ae' User entered 'No (N)'	System	20 Sep 2020 12:07:11
	System	20 Sep 2020 12:07:11

US3522664

Folder: Diary Dose 1 (1)

Form: Swelling_Day(9)

Generated On: 11 Aug 2021 22:53:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-20T08:07:05', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '14579be4-f4eb-4300-9425-e897868bc5ae' User entered '20 Sep 2020 08:07'	System	20 Sep 2020 12:07:11
	System	20 Sep 2020 12:07:11

US3522664

Folder: Diary Dose 1 (1)

Form: Swelling_Day(9)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 21:49:12

US3522664

Folder: Diary Dose 1 (1)

Form: Swelling_Day(9)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 21:49:12

US3522664

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	17 Sep 2020 21:50:30
User entered 'Day 8'	System	17 Sep 2020 21:50:30

US3522664

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:53:30

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-18T17:03:28', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e8004158-3103-481f-9c72-99ea0e53b48f' User entered 'None (0)'	System	18 Sep 2020 21:03:35
	System	18 Sep 2020 21:03:35

US3522664

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:53:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-18T17:03:30', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'e8004158-3103-481f-9c72-99ea0e53b48f' User entered '18 Sep 2020 17:03'	System	18 Sep 2020 21:03:35
	System	18 Sep 2020 21:03:35

US3522664

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 21:50:30

US3522664

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 21:50:30

US3522664

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	16 Sep 2020 19:35:40
User entered 'Day 8'	System	16 Sep 2020 19:35:40

US3522664

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-18T17:03:35', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '538f5802-bb48-4ba1-98a3-0347786c505d' User entered 'No (N)'	System	18 Sep 2020 21:03:41
	System	18 Sep 2020 21:03:41

US3522664

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:53:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-09-18T17:03:38', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '538f5802-bb48-4ba1-98a3-0347786c505d' User entered '18 Sep 2020 17:03'	System	18 Sep 2020 21:03:41
	System	18 Sep 2020 21:03:41

US3522664

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:53:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 19:35:40

US3522664

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:53:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 19:35:40

US3522664

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:13
User entered 'Yes (Y)'	Jo-Ann Rammal (b) (4) (b) (4)	18 Sep 2020 16:54:56

US3522664

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:13
User entered '21 Sep 2020' reason for change: Data Entry Error	Kristin Eis (b) (4)	21 Sep 2020 19:33:35
User entered '18 Sep 2020'	Jo-Ann Rammal (b) (4) (b) (4)	18 Sep 2020 16:54:56

US3522664

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:13
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	21 Sep 2020 19:33:30
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jo-Ann Rammal (b) (4) (b) (4)	18 Sep 2020 16:54:56

US3522664

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:13
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	21 Sep 2020 19:33:30
User entered 'Left voicemail'	Jo-Ann Rammal (b) (4) (b) (4)	18 Sep 2020 16:54:56

US3522664

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:17
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	21 Sep 2020 19:32:15

US3522664

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered 'I'	System	21 Sep 2020 19:32:15

US3522664

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 18:21:36

US3522664

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:22
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 18:21:36

US3522664

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Sep 2020 18:21:36

US3522664

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:22
User entered 'FLARE AT INJECTION SITE NOW REDNESS 120MM BY 86MM. SWELLING 56MM. NO PAIN. NO DOC VISITS. MED OR MED HISTORY CHANGES. NO COVID EXPOSURE. DR Zervos on line discussing with patient.' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 18:25:46
User entered 'Flare at injection site now redness 120mm by 86mm. Swelling 56mm. No pain. No doc visits. Med or med history changes. No COVID exposure.'	(b) (4), (b) (6)	25 Sep 2020 18:21:36

US3522664

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 18:21:41

US3522664

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 05:22:17
User entered 'I'	System	25 Sep 2020 18:21:41

US3522664

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:37:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:25
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:48:18

US3522664

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:37:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:25
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered '2 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:48:18

US3522664

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:37:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:25
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:48:18

US3522664

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:37:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:25
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered "'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'"	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:48:18

US3522664

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:37:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:28
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:48:22

US3522664

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:37:38
User entered 'I'	System	02 Oct 2020 12:48:22

US3522664

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:34
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:45:50

US3522664

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:34
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:45:50

US3522664

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[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 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:34
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Oct 2020 15:45:50

US3522664

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered 'VISIT2'	System	12 Oct 2020 15:45:50

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '11:30'	(b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered '12 Oct 2020 11:30'	System	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '97.4' F	(b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered 'temporal'	(b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '80'	(b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered 'bpm'	System	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '14'	(b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered 'breaths/min'	System	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '156'	(b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered 'mmHg'	System	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '94'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered 'mmHg'	System	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 12:03:30
User entered 'No (N)' reason for change: Data Entry Error	System	14 Oct 2020 12:03:30
User opened query 'Data is required. Please complete.' (Site from System).	Sharon Mathys (b) (4)	14 Oct 2020 12:03:30
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered empty.	System	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered empty.	System	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered empty.	System	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered empty.	System	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered empty.	System	12 Oct 2020 15:51:57

US3522664

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:43
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 15:52:17

US3522664

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:35:43
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:52:17

US3522664

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:01
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'No (N)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	12 Oct 2020 13:09:34

US3522664

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:01
User closed query 'Although source states, treatment held due to previous reaction, there is no corresponding ongoing Adverse Event that precludes treatment. Please kindly advise further and update AE page as required. ' (Site from CRA).	(b) (4), (b) (6)	28 Feb 2021 06:51:17
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
Query 'Although source states, treatment held due to previous reaction, there is no corresponding ongoing Adverse Event that precludes treatment. Please kindly advise further and update AE page as required. ' answered with 'Please see AE log line 1.' (Site from CRA).	(b) (4)	
	Sharon Mathys (b) (4)	07 Dec 2020 17:46:08
	(b) (4)	
User opened query 'Although source states, treatment held due to previous reaction, there is no corresponding ongoing Adverse Event that precludes treatment. Please kindly advise further and update AE page as required. ' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 14:52:36
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Sharon Mathys (b) (4)	12 Oct 2020 13:09:34
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:01
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	12 Oct 2020 13:09:34

US3522664

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered empty.	System	12 Oct 2020 13:09:34

US3522664

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:01
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered empty.	(b) (4)	
	Sharon Mathys (b) (4)	12 Oct 2020 13:09:34
	(b) (4)	

US3522664

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:01
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	12 Oct 2020 13:09:34

US3522664

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered empty.	System	12 Oct 2020 13:09:34

US3522664

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:01
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered empty.	(b) (4)	
	Sharon Mathys (b) (4)	12 Oct 2020 13:09:34
	(b) (4)	

US3522664

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:01
User entered empty.	System	12 Oct 2020 13:09:34

US3522664

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered empty.	System	12 Oct 2020 13:09:34

US3522664

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 15:52:55

US3522664

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:52:55

US3522664

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:05
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '11:42'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:52:55

US3522664

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered '12 Oct 2020 11:42'	System	12 Oct 2020 15:52:55

US3522664

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:53:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:13
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:53:22

US3522664

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	12 Oct 2020 15:53:22

US3522664

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:13
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 15:53:22

US3522664

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:13
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered '11:45'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:53:22

US3522664

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered '12 Oct 2020 11:45'	System	12 Oct 2020 15:53:22

US3522664

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	12 Oct 2020 15:53:22

US3522664

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:13
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 15:53:22

US3522664

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:13
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 15:53:22

US3522664

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered empty.	System	12 Oct 2020 15:53:22

US3522664

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:16
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 15:53:28

US3522664

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered 'I'	System	12 Oct 2020 15:53:28

US3522664

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 18:24:11

US3522664

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 18:24:11

US3522664

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Oct 2020 18:24:11

US3522664

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:24
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'PER THE DISCRETION OF DR. ZERVOS, PATIENT DID NOT RECEIVE IP DURING VISIT 2 DUE TO ADVERSE REACTION FROM THE 1ST INJECTION. THEREFORE, NO EDIARY ENTRY. NO COVID EXPOSURE. HE WILL CONTINUE FOR VISIT 3' reason for change: New Information	(b) (4) (b) (4), (b) (6)	19 Oct 2020 18:26:02
User entered 'Per the discretion of Dr. Zervos, patient did not receive IP during Visit 2 due to adverse reaction from the first injection. No changes in PMH or meds. No COVID exposure. He will continue for Visit 3'	(b) (4), (b) (6)	19 Oct 2020 18:24:11

US3522664

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:35
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 18:25:04

US3522664

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered 'I'	System	19 Oct 2020 18:25:04

US3522664

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:42
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 18:40:36

US3522664

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:42
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered '27 Oct 2020' reason for change: New Information	(b) (4)	
	Yaman Ahmed (b) (4)	27 Oct 2020 14:36:33
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 18:40:36

US3522664

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:42
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: New Information	Yaman Ahmed (b) (4)	27 Oct 2020 14:36:33
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	26 Oct 2020 18:40:36

US3522664

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:42
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, or Covid-19 exposure risk' reason for change: New Information	(b) (4)	
	Yaman Ahmed (b) (4)	27 Oct 2020 14:36:33
	(b) (4)	
User entered 'Voicemail left with callback number and email.'	(b) (4), (b) (6)	26 Oct 2020 18:40:36

US3522664

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	27 Oct 2020 14:36:40

US3522664

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered 'I'	System	27 Oct 2020 14:36:40

US3522664

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'Yes (Y)'	Kristin Eis (b) (4)	02 Nov 2020 17:36:38

US3522664

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered '02 Nov 2020'	Kristin Eis (b) (4)	02 Nov 2020 17:36:38

US3522664

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'Contact Made (CONTACT MADE)'	Kristin Eis (b) (4)	02 Nov 2020 17:36:38

US3522664

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:50
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	Kristin Eis (b) (4)	02 Nov 2020 17:36:38

US3522664

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:36:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:40
User entered 'Yes (Y)'	Kristin Eis (b) (4)	02 Nov 2020 17:36:41

US3522664

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered 'I'	System	02 Nov 2020 17:36:41

US3522664

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	13 Nov 2020 16:25:10

US3522664

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '13 Nov 2020'	(b) (4) Alayna Wilder (b) (4) (b) (4)	13 Nov 2020 16:25:10

US3522664

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[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 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:02
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered 'Clinic (Clinic)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	13 Nov 2020 16:25:10

US3522664

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered 'VISIT3'	System	13 Nov 2020 16:25:10

US3522664

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	13 Nov 2020 16:25:46

US3522664

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '13 Nov 2020'	(b) (4) Alayna Wilder (b) (4) (b) (4)	13 Nov 2020 16:25:46

US3522664

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '11:10'	(b) (4) Alayna Wilder (b) (4) (b) (4)	13 Nov 2020 16:25:46

US3522664

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered '13 Nov 2020 11:10'	System	13 Nov 2020 16:25:46

US3522664

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '97.0' F	(b) (4) Alayna Wilder (b) (4) (b) (4)	13 Nov 2020 16:25:46

US3522664

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered 'Other (Other)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	13 Nov 2020 16:25:46

US3522664

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered 'temporal'	(b) (4) Alayna Wilder (b) (4) (b) (4)	13 Nov 2020 16:25:46

US3522664

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '80'	(b) (4) Alayna Wilder (b) (4) (b) (4)	13 Nov 2020 16:25:46

US3522664

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered 'bpm'	System	13 Nov 2020 16:25:46

US3522664

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '20'	(b) (4) Alayna Wilder (b) (4) (b) (4)	13 Nov 2020 16:25:46

US3522664

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered 'breaths/min'	System	13 Nov 2020 16:25:46

US3522664

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User closed query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate' (Site from DM).	(b) (4)	
Query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate' answered with 'NCS' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 08:48:14
User opened query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate' (Site from DM).	Sharon Mathys (b) (4)	18 Nov 2020 13:46:44
User entered '157'	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 11:10:37
	Alayna Wilder (b) (4)	13 Nov 2020 16:25:46
	(b) (4)	

US3522664

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered 'mmHg'	System	13 Nov 2020 16:25:46

US3522664

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:39
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '91'	(b) (4) Alayna Wilder (b) (4) (b) (4)	13 Nov 2020 16:25:46

US3522664

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered 'mmHg'	System	13 Nov 2020 16:25:46

US3522664

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04

US3522664

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04

US3522664

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:47
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	13 Nov 2020 16:25:54

US3522664

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:47
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '13 Nov 2020'	(b) (4) Alayna Wilder (b) (4) (b) (4)	13 Nov 2020 16:25:54

US3522664

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:51
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	13 Nov 2020 16:26:04

US3522664

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:51
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '13 Nov 2020'	(b) (4) Alayna Wilder (b) (4) (b) (4)	13 Nov 2020 16:26:04

US3522664

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:51
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered '11:20'	(b) (4) Alayna Wilder (b) (4) (b) (4)	13 Nov 2020 16:26:04

US3522664

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered '13 Nov 2020 11:20'	System	13 Nov 2020 16:26:04

US3522664

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:37:54
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:25:44
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	13 Nov 2020 16:26:08

US3522664

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered '1'	System	13 Nov 2020 16:26:08

US3522664

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 64'	System	11 Sep 2020 17:24:57

US3522664

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-11-11T00:11:28', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '54f2f0d6-ab8a-401f-b0ea-27c2ab15745e' User entered 'No (N)'	System	11 Nov 2020 05:11:48
	System	11 Nov 2020 05:11:48

US3522664

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-11-11T00:11:38', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '54f2f0d6-ab8a-401f-b0ea-27c2ab15745e' User entered 'No (N)'	System	11 Nov 2020 05:11:48
	System	11 Nov 2020 05:11:48

US3522664

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-11-11T00:11:45', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '54f2f0d6-ab8a-401f-b0ea-27c2ab15745e' User entered '11 Nov 2020 00:11:45'	System	11 Nov 2020 05:11:48
	System	11 Nov 2020 05:11:48

US3522664

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 17:24:57

US3522664

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered 'Day 71'	System	11 Sep 2020 17:24:57

US3522664

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-11-18T18:21:29', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '8a43dd12-5cb5-4cb1-8211-fc4cad6808c0' User entered 'No (N)'	System	18 Nov 2020 23:21:51
	System	18 Nov 2020 23:21:51

US3522664

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-11-18T18:21:39', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '8a43dd12-5cb5-4cb1-8211-fc4cad6808c0' User entered 'No (N)'	System	18 Nov 2020 23:21:51
	System	18 Nov 2020 23:21:51

US3522664

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-11-18T18:21:48', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '8a43dd12-5cb5-4cb1-8211-fc4cad6808c0' User entered '18 Nov 2020 18:21:48'	System	18 Nov 2020 23:21:51
	System	18 Nov 2020 23:21:51

US3522664

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 17:24:57

US3522664

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:44:31
Data entry locked.	System	11 Sep 2020 17:24:57
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 17:24:57

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-11-22T09:26:17', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '1b82f781-f6d6-4fbf-8c32-7556d7085b42'	System	22 Nov 2020 14:26:58
User entered 'No (N)'	System	22 Nov 2020 14:26:58

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-11-22T09:26:38', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '1b82f781-f6d6-4fbf-8c32-7556d7085b42'	System	22 Nov 2020 14:26:58
User entered 'No (N)'	System	22 Nov 2020 14:26:58

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-11-22T09:26:54', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '1b82f781-f6d6-4fbf-8c32-7556d7085b42'	System	22 Nov 2020 14:26:58
User entered '22 Nov 2020 09:26:54'	System	22 Nov 2020 14:26:58

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-11-29T09:33:21', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '3dfa9fee-f1f9-4563-89dc-bf55279233ca' User entered 'No (N)'	System	29 Nov 2020 14:33:49

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-11-29T09:33:42', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '3dfa9fee-f1f9-4563-89dc-bf55279233ca' User entered 'No (N)'	System	29 Nov 2020 14:33:49

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-11-29T09:33:47', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '3dfa9fee-f1f9-4563-89dc-bf55279233ca' User entered '29 Nov 2020 09:33:47'	System	29 Nov 2020 14:33:49

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-12-06T09:44:31', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '8b8ab670-df7a-47ad-81cd-b2ed9255b5ba' User entered 'No (N)'	System	06 Dec 2020 14:45:00
	System	06 Dec 2020 14:45:00

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-12-06T09:44:45', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '8b8ab670-df7a-47ad-81cd-b2ed9255b5ba' User entered 'No (N)'	System	06 Dec 2020 14:45:00
	System	06 Dec 2020 14:45:00

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-12-06T09:44:54', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '8b8ab670-df7a-47ad-81cd-b2ed9255b5ba' User entered '06 Dec 2020 09:44:54'	System	06 Dec 2020 14:45:00
	System	06 Dec 2020 14:45:00

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-12-13T09:17:06', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '89928919-fce0-465f-810c-ad7ae3af7ed5'	System	13 Dec 2020 14:17:25
User entered 'No (N)'	System	13 Dec 2020 14:17:25

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-12-13T09:17:18', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '89928919-fce0-465f-810c-ad7ae3af7ed5'	System	13 Dec 2020 14:17:25
User entered 'No (N)'	System	13 Dec 2020 14:17:25

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-12-13T09:17:23', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '89928919-fce0-465f-810c-ad7ae3af7ed5' User entered '13 Dec 2020 09:17:23'	System	13 Dec 2020 14:17:25
	System	13 Dec 2020 14:17:25

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-12-21T10:54:59', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'd406b761-e82b-49a1-9704-204bbd57f786'	System	21 Dec 2020 15:55:19
User entered 'No (N)'	System	21 Dec 2020 15:55:19

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-12-21T10:55:10', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'd406b761-e82b-49a1-9704-204bbd57f786'	System	21 Dec 2020 15:55:19
User entered 'No (N)'	System	21 Dec 2020 15:55:19

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-12-21T10:55:15', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'd406b761-e82b-49a1-9704-204bbd57f786' User entered '21 Dec 2020 10:55:15'	System	21 Dec 2020 15:55:19
	System	21 Dec 2020 15:55:19

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-12-27T08:32:58', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'd9dcde9c-7e3d-49f3-871b-d9866cdad2df' User entered 'No (N)'	System	27 Dec 2020 13:33:14
	System	27 Dec 2020 13:33:14

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-12-27T08:33:05', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'd9dcde9c-7e3d-49f3-871b-d9866cdad2df' User entered 'No (N)'	System	27 Dec 2020 13:33:14

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2020-12-27T08:33:10', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'd9dcde9c-7e3d-49f3-871b-d9866cdad2df' User entered '27 Dec 2020 08:33:10'	System	27 Dec 2020 13:33:14
	System	27 Dec 2020 13:33:14

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-01-03T08:52:24', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '0048c8b4-d9b2-4e10-8a5c-6c2b23a13d99'	System	03 Jan 2021 13:52:46
User entered 'No (N)'	System	03 Jan 2021 13:52:46

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-01-03T08:52:36', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '0048c8b4-d9b2-4e10-8a5c-6c2b23a13d99'	System	03 Jan 2021 13:52:46
User entered 'No (N)'	System	03 Jan 2021 13:52:46

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-01-03T08:52:43', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '0048c8b4-d9b2-4e10-8a5c-6c2b23a13d99' User entered '03 Jan 2021 08:52:43'	System	03 Jan 2021 13:52:46
	System	03 Jan 2021 13:52:46

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-01-10T09:01:59', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '439391cf-a8b6-4686-8da3-d962ebafa27e' User entered 'No (N)'	System	10 Jan 2021 14:02:30
	System	10 Jan 2021 14:02:30

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-01-10T09:02:22', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '439391cf-a8b6-4686-8da3-d962ebafa27e' User entered 'No (N)'	System	10 Jan 2021 14:02:30

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-01-10T09:02:28', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '439391cf-a8b6-4686-8da3-d962ebafa27e' User entered '10 Jan 2021 09:02:28'	System	10 Jan 2021 14:02:30

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-01-17T06:02:15', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'a7c4d720-f146-4bb3-91bd-e858a8ed1411'	System	17 Jan 2021 11:02:36
User entered 'No (N)'	System	17 Jan 2021 11:02:36

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-01-17T06:02:27', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'a7c4d720-f146-4bb3-91bd-e858a8ed1411'	System	17 Jan 2021 11:02:36
User entered 'No (N)'	System	17 Jan 2021 11:02:36

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-01-17T06:02:32', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'a7c4d720-f146-4bb3-91bd-e858a8ed1411' User entered '17 Jan 2021 06:02:32'	System	17 Jan 2021 11:02:36
	System	17 Jan 2021 11:02:36

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-01-24T08:43:20', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '7bb0ef52-e4e6-4ca7-81f4-272e8e4fdd9d' User entered 'No (N)'	System	24 Jan 2021 13:43:53
	System	24 Jan 2021 13:43:53

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-01-24T08:43:45', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '7bb0ef52-e4e6-4ca7-81f4-272e8e4fdd9d'	System	24 Jan 2021 13:43:53
User entered 'No (N)'	System	24 Jan 2021 13:43:53

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-01-24T08:43:50', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '7bb0ef52-e4e6-4ca7-81f4-272e8e4fdd9d' User entered '24 Jan 2021 08:43:50'	System	24 Jan 2021 13:43:53

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-01-31T07:45:48', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '149d97db-8d1c-4a18-866a-f63ca01681fb' User entered 'No (N)'	System	31 Jan 2021 12:46:18
	System	31 Jan 2021 12:46:18

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-01-31T07:46:09', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '149d97db-8d1c-4a18-866a-f63ca01681fb' User entered 'No (N)'	System	31 Jan 2021 12:46:18
	System	31 Jan 2021 12:46:18

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-01-31T07:46:13', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '149d97db-8d1c-4a18-866a-f63ca01681fb' User entered '31 Jan 2021 07:46:13'	System	31 Jan 2021 12:46:18
	System	31 Jan 2021 12:46:18

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-02-07T09:04:56', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'a85b4d7b-87af-42e1-8770-a097c55be6ec' User entered 'No (N)'	System	07 Feb 2021 14:05:12
	System	07 Feb 2021 14:05:12

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-02-07T09:05:05', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'a85b4d7b-87af-42e1-8770-a097c55be6ec' User entered 'No (N)'	System	07 Feb 2021 14:05:12

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-02-07T09:05:10', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'a85b4d7b-87af-42e1-8770-a097c55be6ec' User entered '07 Feb 2021 09:05:10'	System	07 Feb 2021 14:05:12

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-02-14T08:29:02', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '6e1de986-627a-4c05-800a-c7d450901c92'	System	14 Feb 2021 13:29:18
User entered 'No (N)'	System	14 Feb 2021 13:29:18

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-02-14T08:29:10', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '6e1de986-627a-4c05-800a-c7d450901c92'	System	14 Feb 2021 13:29:18
User entered 'No (N)'	System	14 Feb 2021 13:29:18

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-02-14T08:29:14', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '6e1de986-627a-4c05-800a-c7d450901c92' User entered '14 Feb 2021 08:29:14'	System	14 Feb 2021 13:29:18
	System	14 Feb 2021 13:29:18

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-02-22T07:43:12', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '33915060-4b3a-42f3-8133-6b5098ebee80' User entered 'No (N)'	System	22 Feb 2021 12:43:24

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-02-22T07:43:17', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '33915060-4b3a-42f3-8133-6b5098ebee80' User entered 'No (N)'	System	22 Feb 2021 12:43:24

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-02-22T07:43:20', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '33915060-4b3a-42f3-8133-6b5098ebee80' User entered '22 Feb 2021 07:43:20'	System	22 Feb 2021 12:43:24
	System	22 Feb 2021 12:43:24

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-02-28T16:07:45', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '801d07a6-36b9-4b01-a06d-be76a54eec70' User entered 'No (N)'	System	28 Feb 2021 21:08:07
	System	28 Feb 2021 21:08:07

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-02-28T16:07:57', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '801d07a6-36b9-4b01-a06d-be76a54eec70'	System	28 Feb 2021 21:08:07
User entered 'No (N)'	System	28 Feb 2021 21:08:07

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-02-28T16:08:02', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '801d07a6-36b9-4b01-a06d-be76a54eec70' User entered '28 Feb 2021 16:08:02'	System	28 Feb 2021 21:08:07
	System	28 Feb 2021 21:08:07

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-03-07T08:11:30', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '40511176-c82f-4a2e-9cca-57c7f4854440'	System	07 Mar 2021 13:11:51
User entered 'No (N)'	System	07 Mar 2021 13:11:51

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-03-07T08:11:37', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '40511176-c82f-4a2e-9cca-57c7f4854440'	System	07 Mar 2021 13:11:51
User entered 'No (N)'	System	07 Mar 2021 13:11:51

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-03-07T08:11:48', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '40511176-c82f-4a2e-9cca-57c7f4854440' User entered '07 Mar 2021 08:11:48'	System	07 Mar 2021 13:11:51
	System	07 Mar 2021 13:11:51

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-03-14T08:54:03', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '7b9a8373-e17f-4551-965f-08231c552909'	System	14 Mar 2021 12:54:16
User entered 'No (N)'	System	14 Mar 2021 12:54:16

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-03-14T08:54:11', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '7b9a8373-e17f-4551-965f-08231c552909'	System	14 Mar 2021 12:54:16
User entered 'No (N)'	System	14 Mar 2021 12:54:16

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-03-14T08:54:14', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '7b9a8373-e17f-4551-965f-08231c552909' User entered '14 Mar 2021 08:54:14'	System	14 Mar 2021 12:54:16
	System	14 Mar 2021 12:54:16

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-03-21T08:46:09', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '70315956-6c29-4b44-b329-17bb3f42bb9e' User entered 'No (N)'	System	21 Mar 2021 12:46:36
	System	21 Mar 2021 12:46:36

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-03-21T08:46:20', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '70315956-6c29-4b44-b329-17bb3f42bb9e'	System	21 Mar 2021 12:46:36
User entered 'No (N)'	System	21 Mar 2021 12:46:36

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-03-21T08:46:32', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '70315956-6c29-4b44-b329-17bb3f42bb9e'	System	21 Mar 2021 12:46:36
User entered '21 Mar 2021 08:46:32'	System	21 Mar 2021 12:46:36

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-03-28T12:42:41-04:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '64a4b89d-3e82-47cc-8fc0-927fc7c0291b'	System	28 Mar 2021 16:42:55
User entered 'No (N)'	System	28 Mar 2021 16:42:55

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-03-28T12:42:49-04:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '64a4b89d-3e82-47cc-8fc0-927fc7c0291b'	System	28 Mar 2021 16:42:55
User entered 'No (N)'	System	28 Mar 2021 16:42:55

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-03-28T12:42:52-04:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '64a4b89d-3e82-47cc-8fc0-927fc7c0291b' User entered '28 Mar 2021 12:42:52'	System	28 Mar 2021 16:42:55
	System	28 Mar 2021 16:42:55

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-04-06T18:47:58-04:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'f9dae59c-97be-401c-a1ea-6cfb74ddc342'	System	06 Apr 2021 22:48:08
User entered 'No (N)'	System	06 Apr 2021 22:48:08

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-04-06T18:48:01-04:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'f9dae59c-97be-401c-a1ea-6cfb74ddc342'	System	06 Apr 2021 22:48:08
User entered 'No (N)'	System	06 Apr 2021 22:48:08

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-04-06T18:48:04-04:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'f9dae59c-97be-401c-a1ea-6cfb74ddc342'	System	06 Apr 2021 22:48:08
User entered '06 Apr 2021 18:48:04'	System	06 Apr 2021 22:48:08

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-04-11T08:11:52-04:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '66f5da1b-8586-4ee4-b2f1-c7f398cfec1b' User entered 'No (N)'	System	11 Apr 2021 12:12:06
	System	11 Apr 2021 12:12:06

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-04-11T08:11:59-04:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '66f5da1b-8586-4ee4-b2f1-c7f398cfec1b' User entered 'No (N)'	System	11 Apr 2021 12:12:06
	System	11 Apr 2021 12:12:06

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-04-11T08:12:04-04:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '66f5da1b-8586-4ee4-b2f1-c7f398cfec1b' User entered '11 Apr 2021 08:12:04'	System	11 Apr 2021 12:12:06
	System	11 Apr 2021 12:12:06

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-04-18T10:01:52-04:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '5becce7c-d2f1-407b-9d99-63e3966134c2' User entered 'No (N)'	System	18 Apr 2021 14:02:08
	System	18 Apr 2021 14:02:08

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-04-18T10:02:00-04:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '5becce7c-d2f1-407b-9d99-63e3966134c2'	System	18 Apr 2021 14:02:08
User entered 'No (N)'	System	18 Apr 2021 14:02:08

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-04-18T10:02:05-04:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '5becce7c-d2f1-407b-9d99-63e3966134c2'	System	18 Apr 2021 14:02:08
User entered '18 Apr 2021 10:02:05'	System	18 Apr 2021 14:02:08

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-04-25T08:12:31-04:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '1d00838e-4b92-42ee-95e4-a98fe782eadf'	System	25 Apr 2021 12:12:52
User entered 'No (N)'	System	25 Apr 2021 12:12:52

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-04-25T08:12:44-04:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '1d00838e-4b92-42ee-95e4-a98fe782eadf'	System	25 Apr 2021 12:12:52
User entered 'No (N)'	System	25 Apr 2021 12:12:52

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-04-25T08:12:50-04:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '1d00838e-4b92-42ee-95e4-a98fe782eadf' User entered '25 Apr 2021 08:12:50'	System	25 Apr 2021 12:12:52
	System	25 Apr 2021 12:12:52

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-05-02T11:54:39-05:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '2f26e8c7-d44b-430e-9465-72a529ae63f2'	System	02 May 2021 16:55:31
User entered 'Yes (Y)'	System	02 May 2021 16:55:31

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

Have you been exposed to someone with 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 (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-05-02T11:54:44-05:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '2f26e8c7-d44b-430e-9465-72a529ae63f2'	System	02 May 2021 16:55:31
User entered 'No (N)'	System	02 May 2021 16:55:31

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-05-02T11:54:57-05:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '2f26e8c7-d44b-430e-9465-72a529ae63f2'	System	02 May 2021 16:55:31
User entered 'No (N)'	System	02 May 2021 16:55:31

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-05-02T11:55:04-05:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '2f26e8c7-d44b-430e-9465-72a529ae63f2'	System	02 May 2021 16:55:31
User entered 'Yes (Y)'	System	02 May 2021 16:55:31

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-05-02T11:55:11-05:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '2f26e8c7-d44b-430e-9465-72a529ae63f2'	System	02 May 2021 16:55:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 May 2021 16:55:31

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-05-02T11:55:19-05:00', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: '2f26e8c7-d44b-430e-9465-72a529ae63f2'	System	02 May 2021 16:55:31
User entered '02 May 2021 11:55:19'	System	02 May 2021 16:55:31

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:40:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:40:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:40:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:40:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:40:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:40:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:40:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:40:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:40:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:40:42

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:40:42

US3522664

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:53:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:40:42
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:40:42

US3522664

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:53:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:36:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-02-28T16:05:57', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'f9d231e7-918c-4457-989f-3422af5f73d5'	System	28 Feb 2021 21:07:33
User entered 'Yes (Y)'	System	28 Feb 2021 21:07:33

US3522664

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:53:30

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:36:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-02-28T16:07:16', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'f9d231e7-918c-4457-989f-3422af5f73d5'	System	28 Feb 2021 21:07:33
User entered 'No (N)'	System	28 Feb 2021 21:07:33

US3522664

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:53:30

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:36:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4F7EC128-3C0A-4A16-B2A5-E6C5BDC8EE5F)', Time: '2021-02-28T16:07:24', User OID: 'PatientReportedOutcome (US3522664)', ODM File OID: 'f9d231e7-918c-4457-989f-3422af5f73d5'	System	28 Feb 2021 21:07:33
User entered '28 Feb 2021 16:07:24'	System	28 Feb 2021 21:07:33

US3522664

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:33:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 18:48:55

US3522664

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:33:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '07 Dec 2020'	(b) (4), (b) (6)	07 Dec 2020 18:48:55

US3522664

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:33:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:48:55

US3522664

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:33:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'redness after 1st inj was flat with no urticaria. Patient states flu vaccine 09/25/202 and not 08/15/2020 as previously documented. No new AE'S etc. See source'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:48:55

US3522664

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:34:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:48:59

US3522664

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:04
User entered 'I'	System	07 Dec 2020 18:48:59

US3522664

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:37:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Jan 2021 19:42:54

US3522664

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:37:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '9 Jan 2021'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Jan 2021 19:42:54

US3522664

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:37:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Jan 2021 19:42:54

US3522664

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:37:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Jan 2021 19:42:54

US3522664

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:38:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	09 Jan 2021 19:43:03

US3522664

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:38
User entered 'I'	System	09 Jan 2021 19:43:03

US3522664

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:41:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Feb 2021 14:32:59

US3522664

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:41:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '9 Feb 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Feb 2021 14:32:59

US3522664

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:41:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Feb 2021 14:32:59

US3522664

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:41:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure'	(b) (4) Yaman Ahmed (b) (4)	09 Feb 2021 14:32:59

US3522664

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:41:13
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Feb 2021 14:33:06

US3522664

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:38
User entered 'I'	System	09 Feb 2021 14:33:06

US3522664

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:43:27
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:42:09
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 15:14:26

US3522664

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:43:27
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:42:09
User entered '9 Mar 2021'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 15:14:26

US3522664

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:43:27
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:42:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 15:14:26

US3522664

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:43:27
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:42:09
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure'	(b) (4) Yaman Ahmed (b) (4)	09 Mar 2021 15:14:26

US3522664

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 18:43:35
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:42:09
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	09 Mar 2021 15:15:09

US3522664

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:20:38
User entered 'I'	System	09 Mar 2021 15:15:09

US3522664

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:39:59
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 14:33:20

US3522664

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:39:59
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered '2 Apr 2021'	(b) (4) Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 14:33:20

US3522664

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:39:59
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered 'Clinic (Clinic)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 14:33:20

US3522664

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
User entered 'VISIT4'	System	02 Apr 2021 14:33:20

US3522664

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:02
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered 'No (N)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 14:33:28

US3522664

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:02
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered empty.	(b) (4) Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 14:33:28

US3522664

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:02
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered empty.	(b) (4) Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 14:33:28

US3522664

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
User entered empty.	System	02 Apr 2021 14:33:28

US3522664

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:02
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered empty.	(b) (4) Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 14:33:28

US3522664

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:02
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered empty.	(b) (4) Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 14:33:28

US3522664

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:02
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered empty.	(b) (4) Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 14:33:28

US3522664

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:02
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered empty.	(b) (4)	
	Alayna Wilder (b) (4)	02 Apr 2021 14:33:28
	(b) (4)	

US3522664

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
User entered empty.	System	02 Apr 2021 14:33:28

US3522664

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:02
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered empty.	(b) (4) Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 14:33:28

US3522664

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
User entered empty.	System	02 Apr 2021 14:33:28

US3522664

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:02
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered empty.	(b) (4) Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 14:33:28

US3522664

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
User entered empty.	System	02 Apr 2021 14:33:28

US3522664

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:02
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered empty.	(b) (4) Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 14:33:28

US3522664

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
User entered empty.	System	02 Apr 2021 14:33:28

US3522664

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09

US3522664

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09

US3522664

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered 'No (N)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 14:33:39

US3522664

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered empty.	(b) (4) Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 14:33:39

US3522664

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 14:33:52

US3522664

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered '2 Apr 2021'	(b) (4) Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 14:33:52

US3522664

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:08
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered '10:25'	(b) (4) Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 14:33:52

US3522664

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
User entered '2 Apr 2021 10:25'	System	02 Apr 2021 14:33:52

US3522664

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:54:11
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 14:34:02

US3522664

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:09
User entered 'I'	System	02 Apr 2021 14:34:02

US3522664

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

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	15 Jan 2021 16:17:08

US3522664

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

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '15 Jan 2021'	(b) (4) Alayna Wilder (b) (4) (b) (4)	15 Jan 2021 16:17:08

US3522664

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

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[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 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:25
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Clinic (Clinic)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	15 Jan 2021 16:17:08

US3522664

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

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 16:17:08

US3522664

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:30

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '15 Jan 2021'	(b) (4) Alayna Wilder (b) (4) (b) (4)	15 Jan 2021 16:17:25

US3522664

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:30

[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 11:33:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:31:56
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:52:53

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:30

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	15 Jan 2021 16:17:25

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:30

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:31:56
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:52:53

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:30

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '15 Jan 2021'	(b) (4) Alayna Wilder (b) (4) (b) (4)	15 Jan 2021 16:17:25

US3522664

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:30

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	15 Jan 2021 16:17:25

US3522664

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:30

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	System	20 Jan 2021 09:23:47
User entered 'mRNA-1273 (mRNA-1273)'	Alayna Wilder (b) (4)	15 Jan 2021 16:17:25
	(b) (4)	

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:30

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Not Administered (NA)' reason for change: Data Entry Error	Alayna Wilder (b) (4)	22 Jan 2021 18:37:03
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	System	20 Jan 2021 09:23:47
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	Alayna Wilder (b) (4)	15 Jan 2021 16:17:45
	(b) (4)	
User entered 'Placebo (Placebo)'	Alayna Wilder (b) (4)	15 Jan 2021 16:17:25
	(b) (4)	

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:30

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User closed query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 09:06:29
Query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' answered with 'Subject did not receive a 2nd dose due to AE, has since been cleared to receive after unblinding. Actual Dose 2 is NONE. ' (Site from System).	Alayna Wilder (b) (4) (b) (4)	15 Jan 2021 16:18:43
User opened query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' (Site from System).	System	15 Jan 2021 16:17:45
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	15 Jan 2021 16:17:25

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:30

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered empty.	System	15 Jan 2021 16:17:25

US3522664

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

Form: Unblinding

Generated On: 11 Aug 2021 22:53:30

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered '1'	System	22 Jan 2021 18:37:03
User entered empty.	System	15 Jan 2021 16:17:45
User entered '1'	System	15 Jan 2021 16:17:25

US3522664

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered missing code ND - Not Done.	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

US3522664

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered missing code ND - Not Done.	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

US3522664

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered empty.	System	09 Feb 2021 14:32:37
DataPoint set to visible.	System	22 Jan 2021 18:37:03

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered missing code ND - Not Done.	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

US3522664

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered missing code ND - Not Done.	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

US3522664

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered empty.	System	09 Feb 2021 14:32:37
DataPoint set to visible.	System	22 Jan 2021 18:37:03

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User accepted default value 'Pre-Dose (PREDOSE)'	Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '15 Jan 2021'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '10:58'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered '15 Jan 2021 10:58'	System	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '98.4' F	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Other (Other)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Temporal'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '68'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered 'bpm'	System	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '20'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered 'breaths/min'	System	09 Feb 2021 14:32:37

US3522664

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '137'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered 'mmHg'	System	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '91'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:53:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered 'mmHg'	System	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered missing code ND - Not Done.	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered missing code ND - Not Done.	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:53:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered empty.	System	09 Feb 2021 14:32:37
DataPoint set to visible.	System	22 Jan 2021 18:37:03

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User accepted default value 'Post-Dose (POSTDOSE)'	Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '15 Jan 2021'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '11:40'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

US3522664

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered '15 Jan 2021 11:40'	System	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '98.4' F	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Other (Other)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

US3522664

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Temporal'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

US3522664

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '64'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered 'bpm'	System	09 Feb 2021 14:32:37

US3522664

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '20'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

US3522664

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered 'breaths/min'	System	09 Feb 2021 14:32:37

US3522664

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '135'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

US3522664

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered 'mmHg'	System	09 Feb 2021 14:32:37

US3522664

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:41
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '87'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:37

US3522664

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:53:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered 'mmHg'	System	09 Feb 2021 14:32:37

US3522664

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:46

US3522664

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '15 Jan 2021'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:32:46

US3522664

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:33:07

US3522664

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered empty.	(b) (4)	
	Sharon Mathys (b) (4)	09 Feb 2021 14:33:07
	(b) (4)	

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

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 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered empty.	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:33:07

US3522664

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered 'mRNA-1273'	System	09 Feb 2021 14:33:07
DataPoint set to visible.	System	22 Jan 2021 18:37:03

US3522664

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '15 Jan 2021'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:33:07

US3522664

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '11:05'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:33:07

US3522664

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered '15 Jan 2021 11:05'	System	09 Feb 2021 14:33:07

US3522664

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	09 Feb 2021 14:33:07

US3522664

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:53
User entered 'ONCE'	System	09 Feb 2021 14:33:07

US3522664

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

Form: Exposure

Generated On: 11 Aug 2021 22:53:30

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 14:33:07

US3522664

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:59
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	15 Jan 2021 16:18:57

US3522664

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:59
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '15 Jan 2021'	(b) (4) Alayna Wilder (b) (4) (b) (4)	15 Jan 2021 16:18:57

US3522664

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:40:59
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '11:00'	(b) (4) Alayna Wilder (b) (4) (b) (4)	15 Jan 2021 16:18:57

US3522664

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered '15 Jan 2021 11:00'	System	15 Jan 2021 16:18:57

US3522664

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:53:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:04
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	15 Jan 2021 16:19:08

US3522664

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:53:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:04
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '15 Jan 2021'	(b) (4) Alayna Wilder (b) (4) (b) (4)	15 Jan 2021 16:19:08

US3522664

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:53:30

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:04
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '11:00'	(b) (4) Alayna Wilder (b) (4) (b) (4)	15 Jan 2021 16:19:08

US3522664

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:53:30

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered '15 Jan 2021 11:00'	System	15 Jan 2021 16:19:08

US3522664

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:09
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 18:37:11

US3522664

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:50
User entered 'I'	System	22 Jan 2021 18:37:11

US3522664

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:38:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 18:37:27

US3522664

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:38:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '22 Jan 2021'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 18:37:27

US3522664

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:38:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 18:37:27

US3522664

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:53:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:38:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 18:37:27

US3522664

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:52
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:38:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 18:37:33

US3522664

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:52
User entered 'I'	System	22 Jan 2021 18:37:33

US3522664

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:53:30

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:52
User entered 'I'	System	22 Jan 2021 18:37:33
DataPoint set to visible.	System	22 Jan 2021 18:37:33

US3522664

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 15:14:53

US3522664

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:14:53

US3522664

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:21
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Feb 2021 15:14:53

US3522664

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:53:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
User entered 'OLD29'	System	12 Feb 2021 15:14:53

US3522664

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:24:23

US3522664

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:24:23

US3522664

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '10:19'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:24:23

US3522664

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
User entered '12 Feb 2021 10:19'	System	12 Feb 2021 15:24:23

US3522664

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '97.7' F	(b) (4), (b) (6)	12 Feb 2021 15:24:23

US3522664

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:24:23

US3522664

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'temporal'	(b) (4), (b) (6)	12 Feb 2021 15:24:23

US3522664

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '69'	(b) (4), (b) (6)	12 Feb 2021 15:24:23

US3522664

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
User entered 'bpm'	System	12 Feb 2021 15:24:23

US3522664

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '16'	(b) (4), (b) (6)	12 Feb 2021 15:24:23

US3522664

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
User entered 'breaths/min'	System	12 Feb 2021 15:24:23

US3522664

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '140'	(b) (4), (b) (6)	12 Feb 2021 15:24:23

US3522664

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
User entered 'mmHg'	System	12 Feb 2021 15:24:23

US3522664

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '88'	(b) (4), (b) (6)	12 Feb 2021 15:24:23

US3522664

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
User entered 'mmHg'	System	12 Feb 2021 15:24:23

US3522664

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31

US3522664

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:53:30

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31

US3522664

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:20:49

US3522664

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:53:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:30
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:20:49

US3522664

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:49
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:35:11

US3522664

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:49
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:35:11

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Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:41:49
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '10:30'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:35:11

US3522664

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:53:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:31
User entered '12 Feb 2021 10:30'	System	12 Feb 2021 15:35:11

US3522664

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:53:30

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:45:54
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 2 diary, UNDERARM GLAND SWELLING or TENDERNESS lasting beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 03:24:05
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 2 diary, UNDERARM GLAND SWELLING or TENDERNESS lasting beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' answered with 'Dose 1: Swelling induration AE added ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 20:11:52
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 2 diary, UNDERARM GLAND SWELLING or TENDERNESS lasting beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 19:12:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 20:01:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 18:22:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site macule, LLT: Injection site macule - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Jan 2021 22:06:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Jan 2021 22:06:52
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site redness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 15:37:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 15:37:46
User closed query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Right deltoid, etc), Type (e.g., Macular, Papular, etc) of REDNESS and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:17:53
Data point term sent to Coder	System	04 Nov 2020 19:01:55
Query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Right deltoid, etc), Type (e.g., Macular, Papular, etc) of REDNESS and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'reviewed with participant and corrected' (Site from DM).	Yaman Ahmed (b) (4) (b) (4)	04 Nov 2020 19:01:32
Coding entries removed.	Yaman Ahmed (b) (4) (b) (4)	04 Nov 2020 19:01:10
User entered 'Right Deltoid macular, non-urticarial REDNESS AT INJECTION SITE 120MM BY 86MM OBLONG' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	04 Nov 2020 19:01:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Right deltoid, etc), Type (e.g., Macular, Papular, etc) of REDNESS and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:08:28
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site redness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 14:17:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 14:17:19
Data point term sent to Coder	System	12 Oct 2020 13:58:09
User closed query 'DM-Coding: Please enter the body site/location of Redness. Please update the reported term.' (Site from System).	System	12 Oct 2020 13:57:52
Query 'DM-Coding: Please enter the body site/location of Redness. Please update the reported term.' answered with 'redness was at injection site. Let us know if there needs to be more clarity' (Site from System).	Sharon Mathys (b) (4) (b) (4)	12 Oct 2020 13:57:52
User entered 'REDNESS at injection site 120MM BY 86MM OBLONG' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	12 Oct 2020 13:57:19
User opened query 'DM-Coding: Please enter the body site/location of Redness. Please update the reported term.' (Site from System).	Coder Import (b) (4) (b) (4)	08 Oct 2020 09:03:16
Data point term sent to Coder	System	25 Sep 2020 18:25:36
User entered 'REDNESS 120mm by 86mm oblong' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 18:24:39
Data point term sent to Coder	System	25 Sep 2020 18:24:34
User entered 'Redness'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:34:24
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:10:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 16:10:13
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:09:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom REDNESS AT INJECTION SITE on 13 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 05:19:46
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom REDNESS AT INJECTION SITE on 13 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' answered with 'See source doc safety call day 15, it was a separate flare up' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:37:20
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom REDNESS AT INJECTION SITE on 13 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:15:30
User entered '23 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	25 Sep 2020 18:24:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 18:24:39
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	25 Sep 2020 18:24:00
User entered '12:00'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 18:24:39
User entered '23 Sep 2020 12:00'	System	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	12 Oct 2020 15:35:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:35:13
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	12 Oct 2020 15:35:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	12 Oct 2020 15:35:06
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	12 Oct 2020 15:35:06
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 15:35:06
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	12 Oct 2020 15:34:14
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 18:24:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered 'Related (RELATED)'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	12 Oct 2020 13:57:31
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	12 Oct 2020 13:57:31
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	12 Oct 2020 13:10:43
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	12 Oct 2020 13:07:36
User entered 'None (NONE)'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered 'I'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	12 Oct 2020 15:34:14
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	25 Sep 2020 18:24:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:55
User entered 'Participant sent an email to report a new development on Day 13; I called him at 11:21 AM today (24 Sep 2020) for clarification. He reports that his original AEs resolved by Day 8-9 and by his Safety call Day 7 (which happened on 21 Sep 2020, which was Day 11) he was fine. But, on 23 Sep 2020 he had a sudden flare at injection site that he describes as a redness of 80 mm with swelling of 62 mm and warm to the touch, also tender with pressure. Today, redness is still spread out, but swelling is down and it is not warm to touch. He did not take any medications 25sep2020 redness oblong shape vertically down and up arm 120mm long wide 86mm. Swelling 56mm long. Relates not painful. Some tenderness. Reported later that it did not last past the 26sep2020.' reason for change: Data Entry Error User entered empty.	Sharon Mathys (b) (4) (b) (4)	07 Dec 2020 17:49:50
	(b) (4), (b) (6)	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Sep 2020 18:24:00

US3522664

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:53:30

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Sep 2020 18:24:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site induration, LLT: Injection site induration - version MedDRA\23.0.	Coder Import (b) (4)	23 Apr 2021 12:13:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Apr 2021 12:13:44
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
Data point term sent to Coder	System	22 Apr 2021 17:18:33
User closed query 'DM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms.	System	22 Apr 2021 17:18:23
' (Site from System).		
Query 'DM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms.	(b) (4), (b) (6)	22 Apr 2021 17:18:23
' answered with 'This is the appropriate term per ecrf completion guidelines. Please advise if different term is needed and update guidelines' (Site from System).		
User opened query 'DM-Coding: Please either provide a single clinical diagnosis for this reported event or split to report each event separately to capture coding for all terms.	Coder Import (b) (4)	21 Apr 2021 12:33:10
' (Site from System).		
Data point term sent to Coder	System	20 Apr 2021 20:12:04
User entered 'Swelling/induration (hardness) at injection site - mild'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered '15 Sep 2020'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

US3522664

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 20:11:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User entered empty.	System	20 Apr 2021 20:11:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered '18 Sep 2020'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

US3522664

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 20:11:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User entered empty.	System	20 Apr 2021 20:11:31

US3522664

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

US3522664

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

US3522664

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

US3522664

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

US3522664

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 20:11:31

US3522664

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 20:11:31

US3522664

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 20:11:31

US3522664

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 20:11:31

US3522664

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

US3522664

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

US3522664

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

US3522664

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered 'Related (RELATED)'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

US3522664

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered 'None (NONE)'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered 'l'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

US3522664

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

US3522664

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	20 Apr 2021 20:11:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 20:11:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:02:09
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 20:11:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User entered '0'	System	20 Apr 2021 20:11:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09
User entered '0'	System	20 Apr 2021 20:11:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:53:30

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:52:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:53:30

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:45:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:01:59
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	19 Oct 2020 18:26:35
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 16:37:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:02:09
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:29:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:29:31
Data point term sent to Coder	System	19 Oct 2020 18:28:24
User entered 'INFLUENZA VACCINATION'	(b) (4), (b) (6)	19 Oct 2020 18:27:46

US3522664

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:02:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 18:27:46

US3522664

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:02:09
User entered 'INFLUENZA PREVENTION'	(b) (4), (b) (6)	19 Oct 2020 18:27:46

US3522664

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:02:09
User entered 'I'	(b) (4), (b) (6)	19 Oct 2020 18:27:46

US3522664

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:02:09
User entered 'Other (OTHER)'	(b) (4), (b) (6)	19 Oct 2020 18:27:46

US3522664

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:02:09
User entered 'INJECTION'	(b) (4), (b) (6)	19 Oct 2020 18:27:46

US3522664

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:02:09
User entered 'once (ONCE)'	(b) (4), (b) (6)	19 Oct 2020 18:27:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:02:09
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 18:27:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:02:09
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	19 Oct 2020 18:27:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:02:09
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 18:27:46

US3522664

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:02:09
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 18:52:03
User entered '15 Aug 2020'	(b) (4), (b) (6)	19 Oct 2020 18:27:46

US3522664

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:02:09
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 18:27:46

US3522664

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:02:09
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 18:27:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 20:02:09
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 18:52:03
User entered '15 Aug 2020'	(b) (4), (b) (6)	19 Oct 2020 18:27:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:02:09
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 18:27:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:27:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:27:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:53:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 18:27:46

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:53:30

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:42:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:37:27

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:53:30

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:42:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered '12 Oct 2020'	(b) (4) Sharon Mathys (b) (4) (b) (4)	12 Oct 2020 13:10:43

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:53:30

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:42:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4)	
reason for change: Data Entry Error	Sharon Mathys (b) (4)	12 Oct 2020 13:57:31
User entered 'Physician decision (specify)	(b) (4)	
(PHYSICIAN DECISION)'	Sharon Mathys (b) (4)	12 Oct 2020 13:10:43
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:53:30

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 08:11:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:42:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:17:34
User closed query 'Per CDM: 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) (4), (b) (6)	24 Nov 2020 13:25:35
Query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) and remove the details' answered with 'updated per request' (Site from DM).	Sharon Mathys (b) (4)	23 Nov 2020 16:02:18
User entered 'AE#1' reason for change: Data Entry Error	(b) (4)	23 Nov 2020 16:02:09
User opened query 'Per CDM: 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 01:48:16
User entered 'BASED ON AE OF REDNESS (LINE 1) PI DECIDED TO WITHHOLD THE SECOND DOSE.' reason for change: Data Entry Error	Sharon Mathys (b) (4)	12 Oct 2020 13:56:57
User entered 'Based on AE of redness (line 1) PI decided to with hold the second dose.'	(b) (4)	12 Oct 2020 13:10:43