

US3522709 (Prod: Henry Ford Health System)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:06:13

All time stamps listed in this document are displayed in GMT

US3522709

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

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[Participant ID](#)

US3522709

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

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US3522709

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:49:09

Generated On: 10 Jun 2021 08:06:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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 19:46:11

Generated On: 10 Jun 2021 08:06:13

Date of Birth (MMM yyyy)	(b) (6) 1994
Age	25
Age Units	YEARS
Age (Derived)	25
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	True
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 19:46:11

Generated On: 10 Jun 2021 08:06:13

Date of Informed Consent ( <i>dd MMM yyyy</i> )	18 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 19:46:11

Generated On: 10 Jun 2021 08:06:13

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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 19:46:11

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Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 19:49:09

Generated On: 10 Jun 2021 08:06:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	18 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	12:40 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 12:40
Height ( <i>xxx.x</i> )	71 in
Weight ( <i>xxx.x</i> )	69 kg
BMI ( <i>xxx.x</i> )	21.21607 kg/m <sup>2</sup>
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 19:46:11

Generated On: 10 Jun 2021 08:06:13

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: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 19:46:11

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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

WORKS AT HOME AND IN  
FACILITY FOR (b) (6)  
(b) (6) IN LOGISTICS

### 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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EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 19:46:11

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:32:48

Generated On: 10 Jun 2021 08:06:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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 19:32:48

Generated On: 10 Jun 2021 08:06:13

What was the date of randomization? (dd MMM yyyy) 18 SEP 2020

What was the participant's randomization number? 114681

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 19:32:48

Generated On: 10 Jun 2021 08:06:13

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 19:32:48

Generated On: 10 Jun 2021 08:06:13

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)	18 SEP 2020
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 12:40
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 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 19:32:48

Generated On: 10 Jun 2021 08:06:13

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)	18 SEP 2020
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 14:15
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 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 19:32:48

Generated On: 10 Jun 2021 08:06:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 19:32:47

Generated On: 10 Jun 2021 08:06:13

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) 18 SEP 2020

What was the treatment time? (00:00-23:59) 13:45 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 13:45

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:32:48

Generated On: 10 Jun 2021 08:06:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 SEP 2020
Collection time (00:00-23:59)	13:05 (24 HR)
Collection date and time (derived)	18 SEP 2020 13:05

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 19:32:47

Generated On: 10 Jun 2021 08:06:13

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:07	18 SEP 2020 13:07
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:32:47

Generated On: 10 Jun 2021 08:06:13

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: 10 Jun 2021 08:06:13

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 14:15

PC Open Date & Time

18 SEP 2020 14:05

PC Close Date & Time

18 SEP 2020 16:35

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**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 98.2 °F

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

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

PC Time Stamp	18 SEP 2020 18:05
PC Open Date & Time	18 SEP 2020 17:30
PC Close Date & Time	19 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 00:05

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59



US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:13

**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

95.8 °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

20 SEP 2020 16:36

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

21 SEP 2020 14:08

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 15:02

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 12:14

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:13

---

**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

94.3 °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

24 SEP 2020 14:14

---

PC Open Date & Time

24 SEP 2020 12:00

---

PC Close Date & Time

25 SEP 2020 11:59

---

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 14:16

PC Open Date & Time

18 SEP 2020 14:05

PC Close Date & Time

18 SEP 2020 16:35

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**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

18 SEP 2020 18:06

PC Open Date & Time

18 SEP 2020 17:30

PC Close Date & Time

19 SEP 2020 11:59

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 00:05

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59



US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 16:37

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 14:09

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 15:02

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 12:15

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 14:14

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**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 ☐

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 14:17
PC Open Date & Time	18 SEP 2020 14:05
PC Close Date & Time	18 SEP 2020 16:35

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**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 ☐



US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 18:06
PC Open Date & Time	18 SEP 2020 17:30
PC Close Date & Time	19 SEP 2020 11:59

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:13

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 ☒

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:13

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 00:06
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:13

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 16:37
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

**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 ☒

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 14:09
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:13

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 15:02
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:13

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 12:15
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:13

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 ☒

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:13

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

US3522709

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:32:47

Generated On: 10 Jun 2021 08:06:13

Was Contact Attempted? Yes ☒  
No ☐

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

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

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

US3522709

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:32:47

Generated On: 10 Jun 2021 08:06:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522709

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:32:47

Generated On: 10 Jun 2021 08:06:13

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 CONTACT MADE AFTER  
SECOND ATTEMPT. NO  
ONGOING OR NEW AE  
REPORTED, NO NEW ILLNESS  
OR HOSPITAL VISITS; NO  
CHANGES IN HEALTH STATUS,  
MEDICATIONS, COVID-19  
EXPOSURE. NO OTHER  
VACCINATIONS.

*If Contact Not Made, please provide Comments*



US3522709

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:32:47

Generated On: 10 Jun 2021 08:06:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522709

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:32:47

Generated On: 10 Jun 2021 08:06:13

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 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

*If Contact Not Made, please provide Comments*

US3522709

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:32:47

Generated On: 10 Jun 2021 08:06:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522709

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:32:48

Generated On: 10 Jun 2021 08:06:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 19:32:48

Generated On: 10 Jun 2021 08:06:13

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)	23 OCT 2020
Time of assessment (00:00-23:59)	14:00 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 14:00
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)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 19:32:48

Generated On: 10 Jun 2021 08:06:13

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)	23 OCT 2020
Time of assessment (00:00-23:59)	14:42 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 14:42
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3522709

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:32:48

Generated On: 10 Jun 2021 08:06:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

US3522709

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 19:32:48

Generated On: 10 Jun 2021 08:06:13

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) 23 OCT 2020

What was the treatment time? (00:00-23:59) 14:12 (24 HR)

Treatment Date and Time (derived) 23 OCT 2020 14:12

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



US3522709

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:32:48

Generated On: 10 Jun 2021 08:06:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 OCT 2020
Collection time (00:00-23:59)	14:05 (24 HR)
Collection date and time (derived)	23 OCT 2020 14:05

US3522709

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 19:32:48

Generated On: 10 Jun 2021 08:06:13

Collection date (dd MMM yyyy)			23 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:07	23 OCT 2020 14:07
Nasopharyngeal Swab 2	No		

US3522709

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:32:48

Generated On: 10 Jun 2021 08:06:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 OCT 2020 14:47

PC Open Date & Time

23 OCT 2020 14:32

PC Close Date & Time

23 OCT 2020 17:02

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.3 °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	23 OCT 2020 19:12
PC Open Date & Time	23 OCT 2020 17:57
PC Close Date & Time	24 OCT 2020 11:59

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 OCT 2020 21:42

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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

25 OCT 2020 17:04

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:13

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

26 OCT 2020 18:52

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59



US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

28 OCT 2020 01:48

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**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

95.9 °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

29 OCT 2020 02:23

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 OCT 2020 19:57

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 OCT 2020 14:47

PC Open Date & Time

23 OCT 2020 14:32

PC Close Date & Time

23 OCT 2020 17:02

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**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

23 OCT 2020 19:13

PC Open Date & Time

23 OCT 2020 17:57

PC Close Date & Time

24 OCT 2020 11:59

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 OCT 2020 21:42

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 OCT 2020 17:04

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 OCT 2020 18:52

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59



US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 OCT 2020 01:48

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 OCT 2020 02:23

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 OCT 2020 19:58

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**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 ☐

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

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

No ☒

Yes ☐

PC Time stamp	23 OCT 2020 14:47
PC Open Date & Time	23 OCT 2020 14:32
PC Close Date & Time	23 OCT 2020 17:02

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**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 ☐

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

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

No ☒

Yes ☐

PC Time stamp	23 OCT 2020 19:13
PC Open Date & Time	23 OCT 2020 17:57
PC Close Date & Time	24 OCT 2020 11:59

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:13

**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 ☒



US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:13

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 21:42
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:13

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 00:20
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 18:52
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:13

Yes <input type="checkbox"/>	
PC Time stamp	28 OCT 2020 01:48
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:13

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 02:23
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:13

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 ☒

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:13

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 19:58
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3522709

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:32:47

Generated On: 10 Jun 2021 08:06:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

LOWER TEMPS IN E-DIARY DUE  
TO WORKPLACE  
THERMOMETER WHICH  
USUALLY REGISTERED LOW  
TEMPS.NO AE REPORTED, NO  
NEW ILLNESS OR HOSPITAL  
VISITS; NO CHANGES IN  
HEALTH STATUS,  
MEDICATIONS, OR COVID-19  
EXPOSURE

US3522709

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:32:47

Generated On: 10 Jun 2021 08:06:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522709

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:32:47

Generated On: 10 Jun 2021 08:06:13

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 NOV 2020

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

Comments CALL ATTEMPTED; VM LEFT  
WITH RETURN CONTACT  
INFORMATION.  
*If Contact Not Made, please provide Comments*

US3522709

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:32:47

Generated On: 10 Jun 2021 08:06:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522709

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:32:47

Generated On: 10 Jun 2021 08:06:13

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 NOV 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.

*If Contact Not Made, please provide Comments*



US3522709

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:32:47

Generated On: 10 Jun 2021 08:06:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522709

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 22:16:12

Generated On: 10 Jun 2021 08:06:13

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

US3522709

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 22:16:12

Generated On: 10 Jun 2021 08:06:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 NOV 2020
Time of assessment (00:00-23:59)	13:58 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 13:58
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522709

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 22:16:12

Generated On: 10 Jun 2021 08:06:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 NOV 2020

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

US3522709

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 22:16:12

Generated On: 10 Jun 2021 08:06:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 NOV 2020
Collection time (00:00-23:59)	14:00 (24 HR)
Collection date and time (derived)	23 NOV 2020 14:00

US3522709

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 22:16:12

Generated On: 10 Jun 2021 08:06:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522709

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59



US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 14:04:27
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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	03 DEC 2020 12:16:27
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☒

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 10:58:17

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 02:19:18
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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	20 DEC 2020 00:09:31
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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

27 DEC 2020 07:11:23

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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	03 JAN 2021 01:01:10
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 11:56:37

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59



US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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	17 JAN 2021 00:12:11
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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

24 JAN 2021 00:30:40

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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

04 FEB 2021 09:38:20

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

<b>TIMEPOINT</b>	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 00:46:59
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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

18 FEB 2021 15:22:09

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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 type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-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"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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21 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 FEB 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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

02 MAR 2021 22:00:09

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59



US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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07 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAR 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 MAR 2021 10:42:26
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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

25 MAR 2021 12:09:06

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 MAR 2021 00:01:33
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

<b>TIMEPOINT</b>	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 APR 2021 00:20:23
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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

11 APR 2021 05:38:18

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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

18 APR 2021 10:53:25

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59



US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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

25 APR 2021 05:55:18

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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

02 MAY 2021 09:06:11

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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 type="radio"/>
Have you been exposed to someone with known SARS-CoV-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"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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06 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 JUN 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐ 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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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13 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 JUN 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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°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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUN 2021 23:59



US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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°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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUL 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐ 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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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18 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUL 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 313

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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22 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 SEP 2021 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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

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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 SEP 2021 23:59



US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 SEP 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 SEP 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	03 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	07 OCT 2021 23:59
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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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



US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	24 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59
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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59



US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2021 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐ 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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 481

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JAN 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 FEB 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 FEB 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 FEB 2022 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐ 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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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27 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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13 MAR 2022 00:01

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17 MAR 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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24 MAR 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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03 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 APR 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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10 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 APR 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 APR 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 MAY 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUN 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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03 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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17 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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°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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59
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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐ 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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	02 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2022 23:59
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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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



US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2022 23:59

US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2022 23:59
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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**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 ☐

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 NOV 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2022 23:59
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US3522709

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:13

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

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2022 23:59

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US3522709

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:06:13

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 22:00:17

US3522709

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:46:11

Generated On: 10 Jun 2021 08:06:13

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 DEC 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

*If Contact Not Made, please provide Comments*

US3522709

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:46:11

Generated On: 10 Jun 2021 08:06:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522709

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:46:11

Generated On: 10 Jun 2021 08:06:13

Was Contact Attempted? Yes ☒  
No ☐

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

*If Contact Not Made, please provide Comments*



US3522709

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:46:11

Generated On: 10 Jun 2021 08:06:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522709

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:46:11

Generated On: 10 Jun 2021 08:06:13

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 FEB 2021

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

Comments LAPAROSCOPIC  
APPENDECTOMY ON 10 FEB  
2021. PRIOR TO SURGERY, HAD  
NAUSEA AND PAIN FOR TWO  
DAYS AND WENT TO URGENT  
CARE THE DAY BEFORE  
SURGERY (09 FEB 2021) THEN  
TO ER. HAS BEEN RECOVERING  
WELL

*If Contact Not Made, please provide Comments*

US3522709

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:46:11

Generated On: 10 Jun 2021 08:06:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522709

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 18:35:23

Generated On: 10 Jun 2021 08:06:13

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 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, NO HX OF FACIAL  
INJECTIONS.

*If Contact Not Made, please provide Comments*

US3522709

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 18:35:23

Generated On: 10 Jun 2021 08:06:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522709

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 12:03:51

Generated On: 10 Jun 2021 08:06:13

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

US3522709

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 12:03:51

Generated On: 10 Jun 2021 08:06:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 APR 2021
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	07 APR 2021 13:50
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522709

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 12:03:51

Generated On: 10 Jun 2021 08:06:13

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Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

07 APR 2021

---

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

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US3522709

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 12:03:51

Generated On: 10 Jun 2021 08:06:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 APR 2021
Collection time (00:00-23:59)	13:52 (24 HR)
Collection date and time (derived)	07 APR 2021 13:52

US3522709

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 12:03:51

Generated On: 10 Jun 2021 08:06:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3522709**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

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*

**US3522709**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3522709

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:06:13

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"/>

**US3522709**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 08:06:13**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3522709

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

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

Visit date (dd MMM yyyy)	27 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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US3522709

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 18:35:22

Generated On: 10 Jun 2021 08:06:13

Date of updated informed consent ( <i>dd MMM yyyy</i> )	27 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> )	27 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1



US3522709

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

Height	
Weight	
BMI (xxx.x)	

US3522709

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

Height	
Weight	
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)	27 JAN 2021
Time of assessment (00:00-23:59)	14:34 (24 HR)
Vital Signs Date and Time (derived)	27 JAN 2021 14:34
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3522709

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

Height	
Weight	
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)	27 JAN 2021
Time of assessment (00:00-23:59)	15:16 (24 HR)
Vital Signs Date and Time (derived)	27 JAN 2021 15:16
Temperature (xxx.x)	98.9 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3522709

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

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 JAN 2021

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

US3522709

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

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

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) 27 JAN 2021

What was the treatment time? (00:00-23:59) 14:46 (24 HR)

Treatment Date and Time (derived) 27 JAN 2021 14:46

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

US3522709

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 JAN 2021
Collection time (00:00-23:59)	14:38 (24 HR)
Collection date and time (derived)	27 JAN 2021 14:38

US3522709

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 JAN 2021
Collection time (00:00 - 23:59)	14:40
Collection Date and Time (derived)	27 JAN 2021 14:40

US3522709

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

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3522709

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:46:11

Generated On: 10 Jun 2021 08:06:13

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 FEB 2021

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

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

*If Contact Not Made, please provide Comments*

US3522709

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:46:11

Generated On: 10 Jun 2021 08:06:13

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

US3522709

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3522709

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 FEB 2021
Time of assessment (00:00-23:59)	14:40 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 14:40
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3522709

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 FEB 2021
Time of assessment (00:00-23:59)	15:29 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 15:29
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3522709

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3522709

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

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

What was the treatment time? (00:00-23:59) 14:59 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 14:59

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

US3522709

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3522709

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:46:11

Generated On: 10 Jun 2021 08:06:13

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 MAR 2021

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

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

*If Contact Not Made, please provide Comments*

US3522709

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:46:11

Generated On: 10 Jun 2021 08:06:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522709

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 12:03:51

Generated On: 10 Jun 2021 08:06:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 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	OLD57

US3522709

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 12:03:51

Generated On: 10 Jun 2021 08:06:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	07 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	13:50 (24 HR)
Vital Signs Date and Time (derived)	07 APR 2021 13:50
Temperature ( <i>xxx.x</i> )	36.9 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	76 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522709

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 12:03:51

Generated On: 10 Jun 2021 08:06:13

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

07 APR 2021

---

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

---

US3522709

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 12:03:51

Generated On: 10 Jun 2021 08:06:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	07 APR 2021
Collection time ( <i>00:00-23:59</i> )	13:52 (24 HR)
Collection date and time (derived)	07 APR 2021 13:52

US3522709

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3522709

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

AEID	USA-US131-2021-MRNA-1273-P30 1000007
Adverse event	APPENDICITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	8 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	11 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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US3522709

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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	False
Concomitant Medication	True
Concomitant Procedure	True
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	

US3522709

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

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LAPAROSCOPIC  
APPENDECTOMY ON 10 FEB  
202, DISCHARGED ON 11 FEB  
2021. COVID-19 NAA TEST DONE  
ON 2/10/2021 WITH NEGATIVE  
RESULTS. PRIOR TO SURGERY,  
HAD NAUSEA AND PAIN FOR  
TWO DAYS AND WENT TO  
URGENT CARE THE DAY  
BEFORE SURGERY (09 FEB 2021)  
WHERE HE WAS GIVEN A  
ZOFRAN INJECTION AND  
LATER ON IN THE DAY HE  
WENT TO ER (BEAUMONT)  
WHERE HE RECEIVED AN IV  
BENADRYL (HE'S NOT SURE OF  
DOSES TO MEDS). POST  
SURGERY, HE'S BEEN  
RECOVERING WELL AND HAS  
NOT HAD TO USE IBUPROFEN  
GIVEN TO HIM AT DISCHARGE.  
HE'S RESUMED MOST OF HIS  
ACTIVITIES THOUGH HE'S  
STILL NOT ALLOWED TO  
BATHE AND LIFT HEAVY  
OBJECTS YET.

---

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

---

US3522709

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

---

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

Yes ☒

No ☐

---

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

---

US3522709

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

Name of Medication ZOFRAN

Prophylaxis Yes ☐  
No ☒

Indication APPENDICITIS

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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US3522709

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	UNKNOWN	
Start date (dd MMM yyyy)	9 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	9 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3522709

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

Name of Medication BENADRYL

Prophylaxis Yes ☐  
No ☒

Indication APPENDICITIS

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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EAB) (1725)

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US3522709

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		9 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3522709

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---



US3522709

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Mar 2021 19:46:10

Generated On: 10 Jun 2021 08:06:13

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 FEB 2021	LAPAROSCOPIC APPENDECTOMY	Adverse Event	

US3522709

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:06:13

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3522709

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:06:13

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 ☐

US3522709

Folder: SAE USA-US131-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 09 Mar 2021 15:42:50

Generated On: 10 Jun 2021 08:06:13

SAEID	USA-US131-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3522709

Folder: SAE USA-US131-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Mar 2021 15:42:50

Generated On: 10 Jun 2021 08:06:13

SAEID	USA-US131-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/FEB/2021 09:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522709

Folder: SAE USA-US131-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Mar 2021 15:42:50

Generated On: 10 Jun 2021 08:06:13

SAEID	USA-US131-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/MAR/2021 09:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522709

Folder: SAE USA-US131-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Mar 2021 15:42:50

Generated On: 10 Jun 2021 08:06:13

SAEID	USA-US131-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	08/MAR/2021 17:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3522709 (Prod: Henry Ford Health System)



**US3522709**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 08:06:13**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'US3522709'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Sep 2020 16:34:12

**US3522709**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:49:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:02

**US3522709**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:49:10
User entered '18 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 16:34:14

**US3522709**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[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 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:49:10
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:02

**US3522709**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User entered 'SCRN'	System	18 Sep 2020 16:47:02

US3522709

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:13

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered (b) (6) 1994'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Sep 2020 16:34:15

**US3522709**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:13**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '25'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:15

**US3522709**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:13**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User entered 'YEARS'	System	18 Sep 2020 16:47:15



**US3522709**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:13**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User entered '25'	System	18 Sep 2020 16:47:38

**US3522709**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:13**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:15

**US3522709**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:13**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:15

**US3522709**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:13**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:15

**US3522709**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:13**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:15

**US3522709**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:13**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:15

**US3522709**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:13**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:15

**US3522709**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:13**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:15



**US3522709**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:13**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:15

**US3522709**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:13**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:15

**US3522709**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:13**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:15

**US3522709**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:06:13**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:15

US3522709

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:13

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:38

**US3522709**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User entered 'Sep 2020'	System	18 Sep 2020 16:47:38

**US3522709**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User entered '2020'	System	18 Sep 2020 16:47:38

**US3522709**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:06:13**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:38



**US3522709**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:38

**US3522709**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:38

**US3522709**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:06:13**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:38

**US3522709**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:06:13**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:47:38

**US3522709**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:06:13**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Sep 2020 16:34:14

**US3522709**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:06:13**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User entered 'I'	System	18 Sep 2020 16:48:05

**US3522709**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:48:05

**US3522709**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 08:06:13**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:56:52



US3522709

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:49:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:57:20

**US3522709**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:49:10
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:57:20

**US3522709**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:49:10
User entered '12:40'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:57:20

**US3522709**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User entered '18 Sep 2020 12:40'	System	18 Sep 2020 16:57:20

US3522709

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:49:10
User entered '71' in	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:57:20
DataPoint set to visible.	System	18 Sep 2020 16:48:05

US3522709

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:49:10
User entered '69' kg	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:57:20
DataPoint set to visible.	System	18 Sep 2020 16:48:05

**US3522709**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User entered '21.21607'	System	18 Sep 2020 16:57:20
DataPoint set to visible.	System	18 Sep 2020 16:48:05

**US3522709**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User entered 'kg/m2'	System	18 Sep 2020 16:57:20
DataPoint set to visible.	System	18 Sep 2020 16:48:05



**US3522709**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:49:10
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:57:20

US3522709

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:49:10
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:57:20

**US3522709**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:49:10
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:57:20

US3522709

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:49:10
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:57:20

**US3522709**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User entered 'bpm'	System	18 Sep 2020 16:57:20

**US3522709**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:49:10
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:57:20

US3522709

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User entered 'breaths/min'	System	18 Sep 2020 16:57:20

**US3522709**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:49:10
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:57:20



**US3522709**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User entered 'mmHg'	System	18 Sep 2020 16:57:20

**US3522709**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:49:10
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:57:20

**US3522709**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User entered 'mmHg'	System	18 Sep 2020 16:57:20

US3522709

Folder: Screening

Form: Vital Signs

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[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35

US3522709

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35

**US3522709**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:06:13**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:57:25

**US3522709**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:06:13**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:57:25

**US3522709**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 08:06:13**

**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 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02



US3522709

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:13

**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 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:13

**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 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:13

**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 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02

US3522709

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:13

[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 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02

US3522709

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:13

[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 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02

US3522709

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:13

**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 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02

US3522709

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:13

**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 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02

US3522709

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:13

[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 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02



US3522709

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:13

**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 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02

US3522709

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:13

**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 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02

**US3522709**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 08:06:13**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02

US3522709

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Works at home and in facility for (b) (6) (b) (6) in logistics'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02

**US3522709**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 08:06:13**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02

US3522709

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02

US3522709

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:13

**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 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02

US3522709

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:13

[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 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:13

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 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02

US3522709

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02

**US3522709**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 08:06:13**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02

**US3522709**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 08:06:13**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:42:35
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:02

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:11

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:11

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:11

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'VISIT1'	System	18 Sep 2020 16:58:11



US3522709

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '18 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 16:44:21

US3522709

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '114681'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Sep 2020 16:44:21

US3522709

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Sep 2020 16:44:21

US3522709

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:21

US3522709

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:21

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:21

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:21

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 08:06:13**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:21



**US3522709**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:43:02
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:31:20
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:31:18

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:06:13**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:48

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:06:13**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:48

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:06:13**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:48

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:06:13**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 16:58:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 16:58:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 16:58:59
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 16:58:48
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:48



**US3522709**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '12:40'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:48

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered '18 Sep 2020 12:40'	System	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '73'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:48

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'bpm'	System	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '16'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:48



US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'breaths/min'	System	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '115'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'mmHg'	System	18 Sep 2020 16:58:48

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '60'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:48

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'mmHg'	System	18 Sep 2020 16:58:48

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:06:13**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:48

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:06:13**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	18 Sep 2020 16:58:48



US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 18:15:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 18:15:39
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 18:15:39
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 16:58:48
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4)	18 Sep 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '14:15' reason for change: Data Entry Error	(b) (4)	18 Sep 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 16:58:48

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered '18 Sep 2020 14:15'	System	18 Sep 2020 18:15:39
User entered empty.	System	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	18 Sep 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Temporal' reason for change: Data Entry Error	(b) (4)	18 Sep 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '70' reason for change: Data Entry Error	(b) (4)	18 Sep 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 16:58:48



US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'bpm'	System	18 Sep 2020 18:15:39
User entered empty.	System	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '14' reason for change: Data Entry Error	(b) (4)	18 Sep 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'breaths/min'	System	18 Sep 2020 18:15:39
User entered empty.	System	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '103' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'mmHg'	System	18 Sep 2020 18:15:39
User entered empty.	System	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '70' reason for change: Data Entry Error	(b) (4)	18 Sep 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'mmHg'	System	18 Sep 2020 18:15:39
User entered empty.	System	18 Sep 2020 16:58:48

US3522709

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:55



**US3522709**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:06:13**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:58:55

US3522709

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:03:21

US3522709

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:03:21

US3522709

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:03:21

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:03:21

US3522709

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '13:45'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:03:21

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered '18 Sep 2020 13:45'	System	18 Sep 2020 18:03:21



US3522709

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:13

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:03:21

US3522709

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'ONCE'	System	18 Sep 2020 18:03:21

US3522709

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 18:03:21

US3522709

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:59:11

US3522709

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:59:11

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '13:05'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:59:11

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered '18 Sep 2020 13:05'	System	18 Sep 2020 16:59:11

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 08:06:13**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:59:22



**US3522709**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	18 Sep 2020 16:59:22

US3522709

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:59:22

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '13:07'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:59:22

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered '18 Sep 2020 13:07'	System	18 Sep 2020 16:59:22

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	18 Sep 2020 16:59:22

US3522709

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:59:22

US3522709

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:59:22

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered empty.	System	18 Sep 2020 16:59:22



US3522709

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:59:27

**US3522709**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'I'	System	18 Sep 2020 16:59:27

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T14:15:10', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '93beaff6-28d8-446f-9693-f5fd00f2aea0'	System	18 Sep 2020 18:16:10
User entered 'Yes (Y)'	System	18 Sep 2020 18:16:10

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T14:15:15', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '93beaff6-28d8-446f-9693-f5fd00f2aea0'	System	18 Sep 2020 18:16:10
User entered '98.2'	System	18 Sep 2020 18:16:10

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T14:15:54', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '93beaff6-28d8-446f-9693-f5fd00f2aea0'	System	18 Sep 2020 18:16:10
User entered 'No (N)'	System	18 Sep 2020 18:16:10

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T14:15:58', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '93beaff6-28d8-446f-9693-f5fd00f2aea0'	System	18 Sep 2020 18:16:10
User entered '18 Sep 2020 14:15'	System	18 Sep 2020 18:16:10

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '18 Sep 2020 14:05'	System	18 Sep 2020 18:03:21



**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '18 Sep 2020 16:35'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T18:05:47', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'd264de63-5bec-4167-b2cc-6cab9aa684a4'	System	18 Sep 2020 22:06:01
User entered 'Yes (Y)'	System	18 Sep 2020 22:06:01

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T18:05:50', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'd264de63-5bec-4167-b2cc-6cab9aa684a4'	System	18 Sep 2020 22:06:01
User entered '98.2'	System	18 Sep 2020 22:06:01

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T18:05:54', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'd264de63-5bec-4167-b2cc-6cab9aa684a4'	System	18 Sep 2020 22:06:01
User entered 'No (N)'	System	18 Sep 2020 22:06:01

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T18:05:56', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'd264de63-5bec-4167-b2cc-6cab9aa684a4'	System	18 Sep 2020 22:06:01
User entered '18 Sep 2020 18:05'	System	18 Sep 2020 22:06:01

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '18 Sep 2020 17:30'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 18:03:21



US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 2'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T00:05:11', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c49c951b-6182-429a-831a-7b49533a924c'	System	20 Sep 2020 04:05:28
User entered 'Yes (Y)'	System	20 Sep 2020 04:05:28

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T00:05:20', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c49c951b-6182-429a-831a-7b49533a924c'	System	20 Sep 2020 04:05:28
User entered '96.5'	System	20 Sep 2020 04:05:28

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T00:05:22', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c49c951b-6182-429a-831a-7b49533a924c'	System	20 Sep 2020 04:05:28
User entered 'No (N)'	System	20 Sep 2020 04:05:28

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T00:05:24', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c49c951b-6182-429a-831a-7b49533a924c'	System	20 Sep 2020 04:05:28
User entered '20 Sep 2020 00:05'	System	20 Sep 2020 04:05:28

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 3'	System	18 Sep 2020 18:03:21



US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T16:36:36', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'ad9a7209-1a70-4ea6-ba0a-6a717732f718'	System	20 Sep 2020 20:36:48
User entered 'Yes (Y)'	System	20 Sep 2020 20:36:48

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T16:36:40', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'ad9a7209-1a70-4ea6-ba0a-6a717732f718'	System	20 Sep 2020 20:36:48
User entered '95.8'	System	20 Sep 2020 20:36:48

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T16:36:43', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'ad9a7209-1a70-4ea6-ba0a-6a717732f718'	System	20 Sep 2020 20:36:48
User entered 'No (N)'	System	20 Sep 2020 20:36:48

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T16:36:45', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'ad9a7209-1a70-4ea6-ba0a-6a717732f718'	System	20 Sep 2020 20:36:48
User entered '20 Sep 2020 16:36'	System	20 Sep 2020 20:36:48

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 4'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-21T14:08:41', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '04d00aec-dbd2-4635-b57a-d19f1de61d3d'	System	21 Sep 2020 18:09:08
User entered 'Yes (Y)'	System	21 Sep 2020 18:09:08



US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-21T14:08:52', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '04d00aec-dbd2-4635-b57a-d19f1de61d3d'	System	21 Sep 2020 18:09:08
User entered '97.1'	System	21 Sep 2020 18:09:08

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-21T14:08:56', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '04d00aec-dbd2-4635-b57a-d19f1de61d3d'	System	21 Sep 2020 18:09:08
User entered 'No (N)'	System	21 Sep 2020 18:09:08

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-21T14:08:59', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '04d00aec-dbd2-4635-b57a-d19f1de61d3d'	System	21 Sep 2020 18:09:08
User entered '21 Sep 2020 14:08'	System	21 Sep 2020 18:09:08

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 5'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-22T15:01:53', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '8969d968-18f4-4900-b65f-ca29c2eacfcf'	System	22 Sep 2020 19:02:06
User entered 'Yes (Y)'	System	22 Sep 2020 19:02:06

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-22T15:01:56', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '8969d968-18f4-4900-b65f-ca29c2eacfcf'	System	22 Sep 2020 19:02:06
User entered '98.3'	System	22 Sep 2020 19:02:06



US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-22T15:01:58', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '8969d968-18f4-4900-b65f-ca29c2eacfcf'	System	22 Sep 2020 19:02:06
User entered 'No (N)'	System	22 Sep 2020 19:02:06

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-22T15:02:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '8969d968-18f4-4900-b65f-ca29c2eacfcf'	System	22 Sep 2020 19:02:06
User entered '22 Sep 2020 15:02'	System	22 Sep 2020 19:02:06

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 6'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-23T12:14:52', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '42cc8681-7594-4d2d-9025-81b75890aaa8'	System	23 Sep 2020 16:15:05
User entered 'Yes (Y)'	System	23 Sep 2020 16:15:05

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-23T12:14:55', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '42cc8681-7594-4d2d-9025-81b75890aaa8'	System	23 Sep 2020 16:15:05
User entered '97.4'	System	23 Sep 2020 16:15:05

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-23T12:14:57', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '42cc8681-7594-4d2d-9025-81b75890aaa8'	System	23 Sep 2020 16:15:05
User entered 'No (N)'	System	23 Sep 2020 16:15:05



**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-23T12:14:59', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '42cc8681-7594-4d2d-9025-81b75890aaa8'	System	23 Sep 2020 16:15:05
User entered '23 Sep 2020 12:14'	System	23 Sep 2020 16:15:05

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 7'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-24T14:14:24', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b1b2d0be-82db-4bb0-9a0a-fb7c24f0fad3'	System	24 Sep 2020 18:14:35
User entered 'Yes (Y)'	System	24 Sep 2020 18:14:35

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-24T14:14:27', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b1b2d0be-82db-4bb0-9a0a-fb7c24f0fad3'	System	24 Sep 2020 18:14:35
User entered '94.3'	System	24 Sep 2020 18:14:35

US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-24T14:14:29', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b1b2d0be-82db-4bb0-9a0a-fb7c24f0fad3'	System	24 Sep 2020 18:14:35
User entered 'No (N)'	System	24 Sep 2020 18:14:35

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-24T14:14:31', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b1b2d0be-82db-4bb0-9a0a-fb7c24f0fad3'	System	24 Sep 2020 18:14:35
User entered '24 Sep 2020 14:14'	System	24 Sep 2020 18:14:35



US3522709

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T14:16:16', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'e4b216ef-06db-454c-9154-7f801032d77a'	System	18 Sep 2020 18:16:30
User entered 'None (1)'	System	18 Sep 2020 18:16:30

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T14:16:19', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'e4b216ef-06db-454c-9154-7f801032d77a'	System	18 Sep 2020 18:16:30
User entered 'No (N)'	System	18 Sep 2020 18:16:30

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T14:16:21', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'e4b216ef-06db-454c-9154-7f801032d77a'	System	18 Sep 2020 18:16:30
User entered 'No (N)'	System	18 Sep 2020 18:16:30

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T14:16:25', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'e4b216ef-06db-454c-9154-7f801032d77a'	System	18 Sep 2020 18:16:30
User entered 'None (1)'	System	18 Sep 2020 18:16:30

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T14:16:27', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'e4b216ef-06db-454c-9154-7f801032d77a'	System	18 Sep 2020 18:16:30
User entered '18 Sep 2020 14:16'	System	18 Sep 2020 18:16:30



US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '18 Sep 2020 14:05'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '18 Sep 2020 16:35'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T18:06:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '62bc71bc-bed1-4295-94a8-2a8852f7c2fb'	System	18 Sep 2020 22:06:18
User entered 'None (1)'	System	18 Sep 2020 22:06:18

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T18:06:03', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '62bc71bc-bed1-4295-94a8-2a8852f7c2fb'	System	18 Sep 2020 22:06:18
User entered 'No (N)'	System	18 Sep 2020 22:06:18

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T18:06:05', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '62bc71bc-bed1-4295-94a8-2a8852f7c2fb'	System	18 Sep 2020 22:06:18
User entered 'No (N)'	System	18 Sep 2020 22:06:18

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T18:06:07', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '62bc71bc-bed1-4295-94a8-2a8852f7c2fb'	System	18 Sep 2020 22:06:18
User entered 'None (1)'	System	18 Sep 2020 22:06:18

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T18:06:12', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '62bc71bc-bed1-4295-94a8-2a8852f7c2fb'	System	18 Sep 2020 22:06:18
User entered '18 Sep 2020 18:06'	System	18 Sep 2020 22:06:18



**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '18 Sep 2020 17:30'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 2'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T00:05:33', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'de23e1fc-02b1-4f54-8362-c1e6af1271ed'	System	20 Sep 2020 04:05:50
User entered 'Does not interfere with activity (2)'	System	20 Sep 2020 04:05:50

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T00:05:38', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'de23e1fc-02b1-4f54-8362-c1e6af1271ed'	System	20 Sep 2020 04:05:50
User entered 'No (N)'	System	20 Sep 2020 04:05:50

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T00:05:40', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'de23e1fc-02b1-4f54-8362-c1e6af1271ed'	System	20 Sep 2020 04:05:50
User entered 'No (N)'	System	20 Sep 2020 04:05:50

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T00:05:43', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'de23e1fc-02b1-4f54-8362-c1e6af1271ed'	System	20 Sep 2020 04:05:50
User entered 'None (1)'	System	20 Sep 2020 04:05:50

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T00:05:45', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'de23e1fc-02b1-4f54-8362-c1e6af1271ed'	System	20 Sep 2020 04:05:50
User entered '20 Sep 2020 00:05'	System	20 Sep 2020 04:05:50



**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 3'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T16:36:52', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b41ccd0b-f013-4171-9699-a21f8f883f79'	System	20 Sep 2020 20:37:11
User entered 'None (1)'	System	20 Sep 2020 20:37:11

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T16:36:58', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b41ccd0b-f013-4171-9699-a21f8f883f79'	System	20 Sep 2020 20:37:11
User entered 'No (N)'	System	20 Sep 2020 20:37:11

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T16:37:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b41ccd0b-f013-4171-9699-a21f8f883f79'	System	20 Sep 2020 20:37:11
User entered 'No (N)'	System	20 Sep 2020 20:37:11

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T16:37:03', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b41ccd0b-f013-4171-9699-a21f8f883f79'	System	20 Sep 2020 20:37:11
User entered 'None (1)'	System	20 Sep 2020 20:37:11

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T16:37:05', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b41ccd0b-f013-4171-9699-a21f8f883f79'	System	20 Sep 2020 20:37:11
User entered '20 Sep 2020 16:37'	System	20 Sep 2020 20:37:11



**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 4'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-21T14:09:04', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6244d9e1-76f1-4376-b496-c7da5501a5ab'	System	21 Sep 2020 18:09:23
User entered 'None (1)'	System	21 Sep 2020 18:09:23

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-21T14:09:07', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6244d9e1-76f1-4376-b496-c7da5501a5ab'	System	21 Sep 2020 18:09:23
User entered 'No (N)'	System	21 Sep 2020 18:09:23

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-21T14:09:09', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6244d9e1-76f1-4376-b496-c7da5501a5ab'	System	21 Sep 2020 18:09:23
User entered 'No (N)'	System	21 Sep 2020 18:09:23

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-21T14:09:12', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6244d9e1-76f1-4376-b496-c7da5501a5ab'	System	21 Sep 2020 18:09:23
User entered 'None (1)'	System	21 Sep 2020 18:09:23

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-21T14:09:16', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6244d9e1-76f1-4376-b496-c7da5501a5ab'	System	21 Sep 2020 18:09:23
User entered '21 Sep 2020 14:09'	System	21 Sep 2020 18:09:23



**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 5'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-22T15:02:04', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6616c72e-5a97-49ac-8970-6ba3134859bb'	System	22 Sep 2020 19:02:14
User entered 'None (1)'	System	22 Sep 2020 19:02:14

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-22T15:02:05', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6616c72e-5a97-49ac-8970-6ba3134859bb'	System	22 Sep 2020 19:02:14
User entered 'No (N)'	System	22 Sep 2020 19:02:14

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-22T15:02:07', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6616c72e-5a97-49ac-8970-6ba3134859bb'	System	22 Sep 2020 19:02:14
User entered 'No (N)'	System	22 Sep 2020 19:02:14

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-22T15:02:09', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6616c72e-5a97-49ac-8970-6ba3134859bb'	System	22 Sep 2020 19:02:14
User entered 'None (1)'	System	22 Sep 2020 19:02:14

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-22T15:02:11', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6616c72e-5a97-49ac-8970-6ba3134859bb'	System	22 Sep 2020 19:02:14
User entered '22 Sep 2020 15:02'	System	22 Sep 2020 19:02:14



**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 6'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-23T12:15:03', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '7495664c-cd59-42fe-8550-9710cfd4687d'	System	23 Sep 2020 16:15:17
User entered 'None (1)'	System	23 Sep 2020 16:15:17

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-23T12:15:05', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '7495664c-cd59-42fe-8550-9710cfd4687d'	System	23 Sep 2020 16:15:17
User entered 'No (N)'	System	23 Sep 2020 16:15:17

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-23T12:15:06', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '7495664c-cd59-42fe-8550-9710cfd4687d'	System	23 Sep 2020 16:15:17
User entered 'No (N)'	System	23 Sep 2020 16:15:17

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-23T12:15:08', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '7495664c-cd59-42fe-8550-9710cfd4687d'	System	23 Sep 2020 16:15:17
User entered 'None (1)'	System	23 Sep 2020 16:15:17

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-23T12:15:10', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '7495664c-cd59-42fe-8550-9710cfd4687d'	System	23 Sep 2020 16:15:17
User entered '23 Sep 2020 12:15'	System	23 Sep 2020 16:15:17



**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 7'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-24T14:14:34', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'a5427d46-c325-4daf-9859-ca55a94fd9c8'	System	24 Sep 2020 18:14:44
User entered 'None (1)'	System	24 Sep 2020 18:14:44

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-24T14:14:36', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'a5427d46-c325-4daf-9859-ca55a94fd9c8'	System	24 Sep 2020 18:14:44
User entered 'No (N)'	System	24 Sep 2020 18:14:44

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-24T14:14:38', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'a5427d46-c325-4daf-9859-ca55a94fd9c8'	System	24 Sep 2020 18:14:44
User entered 'No (N)'	System	24 Sep 2020 18:14:44

US3522709

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-24T14:14:39', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'a5427d46-c325-4daf-9859-ca55a94fd9c8'	System	24 Sep 2020 18:14:44
User entered 'None (1)'	System	24 Sep 2020 18:14:44

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-24T14:14:41', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'a5427d46-c325-4daf-9859-ca55a94fd9c8'	System	24 Sep 2020 18:14:44
User entered '24 Sep 2020 14:14'	System	24 Sep 2020 18:14:44



**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T14:16:33', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '8b6bbfe8-1215-470c-a6da-a26d0ee84357'	System	18 Sep 2020 18:17:08
User entered 'None (0)'	System	18 Sep 2020 18:17:08

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T14:16:34', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '8b6bbfe8-1215-470c-a6da-a26d0ee84357'	System	18 Sep 2020 18:17:08
User entered 'None (0)'	System	18 Sep 2020 18:17:08

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T14:16:36', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '8b6bbfe8-1215-470c-a6da-a26d0ee84357'	System	18 Sep 2020 18:17:08
User entered 'None (0)'	System	18 Sep 2020 18:17:08

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T14:16:38', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '8b6bbfe8-1215-470c-a6da-a26d0ee84357'	System	18 Sep 2020 18:17:08
User entered 'None (0)'	System	18 Sep 2020 18:17:08

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T14:16:39', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '8b6bbfe8-1215-470c-a6da-a26d0ee84357'	System	18 Sep 2020 18:17:08
User entered 'None (0)'	System	18 Sep 2020 18:17:08



US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T14:16:40', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '8b6bbfe8-1215-470c-a6da-a26d0ee84357'	System	18 Sep 2020 18:17:08
User entered 'None (0)'	System	18 Sep 2020 18:17:08

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T14:17:03', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '8b6bbfe8-1215-470c-a6da-a26d0ee84357'	System	18 Sep 2020 18:17:08
User entered 'No (N)'	System	18 Sep 2020 18:17:08

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T14:17:05', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '8b6bbfe8-1215-470c-a6da-a26d0ee84357'	System	18 Sep 2020 18:17:08
User entered '18 Sep 2020 14:17'	System	18 Sep 2020 18:17:08

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '18 Sep 2020 14:05'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '18 Sep 2020 16:35'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T18:06:15', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '74ee0e3f-77dd-4b47-9671-1535c79d0ebf'	System	18 Sep 2020 22:06:33
User entered 'None (0)'	System	18 Sep 2020 22:06:33

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T18:06:16', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '74ee0e3f-77dd-4b47-9671-1535c79d0ebf'	System	18 Sep 2020 22:06:33
User entered 'None (0)'	System	18 Sep 2020 22:06:33



US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T18:06:18', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '74ee0e3f-77dd-4b47-9671-1535c79d0ebf'	System	18 Sep 2020 22:06:33
User entered 'None (0)'	System	18 Sep 2020 22:06:33

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T18:06:19', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '74ee0e3f-77dd-4b47-9671-1535c79d0ebf'	System	18 Sep 2020 22:06:33
User entered 'None (0)'	System	18 Sep 2020 22:06:33

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T18:06:20', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '74ee0e3f-77dd-4b47-9671-1535c79d0ebf'	System	18 Sep 2020 22:06:33
User entered 'None (0)'	System	18 Sep 2020 22:06:33

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T18:06:21', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '74ee0e3f-77dd-4b47-9671-1535c79d0ebf'	System	18 Sep 2020 22:06:33
User entered 'None (0)'	System	18 Sep 2020 22:06:33

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T18:06:24', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '74ee0e3f-77dd-4b47-9671-1535c79d0ebf'	System	18 Sep 2020 22:06:33
User entered 'No (N)'	System	18 Sep 2020 22:06:33

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-18T18:06:26', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '74ee0e3f-77dd-4b47-9671-1535c79d0ebf'	System	18 Sep 2020 22:06:33
User entered '18 Sep 2020 18:06'	System	18 Sep 2020 22:06:33

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '18 Sep 2020 17:30'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 18:03:21



US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 2'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T00:05:49', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c8d6acae-f963-4152-8cbe-58089338d960'	System	20 Sep 2020 04:06:04
User entered 'None (0)'	System	20 Sep 2020 04:06:04

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T00:05:50', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c8d6acae-f963-4152-8cbe-58089338d960'	System	20 Sep 2020 04:06:04
User entered 'None (0)'	System	20 Sep 2020 04:06:04

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T00:05:52', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c8d6acae-f963-4152-8cbe-58089338d960'	System	20 Sep 2020 04:06:04
User entered 'None (0)'	System	20 Sep 2020 04:06:04

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T00:05:54', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c8d6acae-f963-4152-8cbe-58089338d960'	System	20 Sep 2020 04:06:04
User entered 'None (0)'	System	20 Sep 2020 04:06:04

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T00:05:55', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c8d6acae-f963-4152-8cbe-58089338d960'	System	20 Sep 2020 04:06:04
User entered 'None (0)'	System	20 Sep 2020 04:06:04

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T00:05:56', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c8d6acae-f963-4152-8cbe-58089338d960'	System	20 Sep 2020 04:06:04
User entered 'None (0)'	System	20 Sep 2020 04:06:04

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T00:05:59', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c8d6acae-f963-4152-8cbe-58089338d960'	System	20 Sep 2020 04:06:04
User entered 'No (N)'	System	20 Sep 2020 04:06:04



**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T00:06:01', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c8d6acae-f963-4152-8cbe-58089338d960'	System	20 Sep 2020 04:06:04
User entered '20 Sep 2020 00:06'	System	20 Sep 2020 04:06:04

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 3'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T16:37:08', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'cfd57a13-fb92-44ca-a96f-6c34145ad719'	System	20 Sep 2020 20:37:23
User entered 'None (0)'	System	20 Sep 2020 20:37:23

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T16:37:09', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'cfd57a13-fb92-44ca-a96f-6c34145ad719'	System	20 Sep 2020 20:37:23
User entered 'None (0)'	System	20 Sep 2020 20:37:23

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T16:37:10', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'cfd57a13-fb92-44ca-a96f-6c34145ad719'	System	20 Sep 2020 20:37:23
User entered 'None (0)'	System	20 Sep 2020 20:37:23

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T16:37:12', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'cfd57a13-fb92-44ca-a96f-6c34145ad719'	System	20 Sep 2020 20:37:23
User entered 'None (0)'	System	20 Sep 2020 20:37:23



**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T16:37:13', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'cfd57a13-fb92-44ca-a96f-6c34145ad719'	System	20 Sep 2020 20:37:23
User entered 'None (0)'	System	20 Sep 2020 20:37:23

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T16:37:14', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'cfd57a13-fb92-44ca-a96f-6c34145ad719'	System	20 Sep 2020 20:37:23
User entered 'None (0)'	System	20 Sep 2020 20:37:23

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T16:37:18', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'cfd57a13-fb92-44ca-a96f-6c34145ad719'	System	20 Sep 2020 20:37:23
User entered 'No (N)'	System	20 Sep 2020 20:37:23

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-20T16:37:20', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'cfd57a13-fb92-44ca-a96f-6c34145ad719'	System	20 Sep 2020 20:37:23
User entered '20 Sep 2020 16:37'	System	20 Sep 2020 20:37:23

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 4'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:06:13**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-21T14:09:20', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '42420448-86bd-43ce-9c13-550be241c5da'	System	21 Sep 2020 18:09:46
User entered 'None (0)'	System	21 Sep 2020 18:09:46



US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-21T14:09:25', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '42420448-86bd-43ce-9c13-550be241c5da'	System	21 Sep 2020 18:09:46
User entered 'None (0)'	System	21 Sep 2020 18:09:46

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-21T14:09:28', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '42420448-86bd-43ce-9c13-550be241c5da'	System	21 Sep 2020 18:09:46
User entered 'None (0)'	System	21 Sep 2020 18:09:46

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-21T14:09:31', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '42420448-86bd-43ce-9c13-550be241c5da'	System	21 Sep 2020 18:09:46
User entered 'None (0)'	System	21 Sep 2020 18:09:46

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:06:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-21T14:09:33', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '42420448-86bd-43ce-9c13-550be241c5da'	System	21 Sep 2020 18:09:46
User entered 'None (0)'	System	21 Sep 2020 18:09:46

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-21T14:09:35', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '42420448-86bd-43ce-9c13-550be241c5da'	System	21 Sep 2020 18:09:46
User entered 'None (0)'	System	21 Sep 2020 18:09:46

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-21T14:09:38', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '42420448-86bd-43ce-9c13-550be241c5da'	System	21 Sep 2020 18:09:46
User entered 'No (N)'	System	21 Sep 2020 18:09:46

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-21T14:09:41', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '42420448-86bd-43ce-9c13-550be241c5da'	System	21 Sep 2020 18:09:46
User entered '21 Sep 2020 14:09'	System	21 Sep 2020 18:09:46

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 18:03:21



**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 5'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-22T15:02:14', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '302a7684-9e4e-4e98-a122-ae89bc6d3c47'	System	22 Sep 2020 19:02:27
User entered 'None (0)'	System	22 Sep 2020 19:02:27

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-22T15:02:15', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '302a7684-9e4e-4e98-a122-ae89bc6d3c47'	System	22 Sep 2020 19:02:27
User entered 'None (0)'	System	22 Sep 2020 19:02:27

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-22T15:02:16', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '302a7684-9e4e-4e98-a122-ae89bc6d3c47'	System	22 Sep 2020 19:02:27
User entered 'None (0)'	System	22 Sep 2020 19:02:27

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-22T15:02:17', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '302a7684-9e4e-4e98-a122-ae89bc6d3c47'	System	22 Sep 2020 19:02:27
User entered 'None (0)'	System	22 Sep 2020 19:02:27

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-22T15:02:18', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '302a7684-9e4e-4e98-a122-ae89bc6d3c47'	System	22 Sep 2020 19:02:27
User entered 'None (0)'	System	22 Sep 2020 19:02:27

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-22T15:02:19', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '302a7684-9e4e-4e98-a122-ae89bc6d3c47'	System	22 Sep 2020 19:02:27
User entered 'None (0)'	System	22 Sep 2020 19:02:27



US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-22T15:02:21', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '302a7684-9e4e-4e98-a122-ae89bc6d3c47'	System	22 Sep 2020 19:02:27
User entered 'No (N)'	System	22 Sep 2020 19:02:27

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-22T15:02:23', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '302a7684-9e4e-4e98-a122-ae89bc6d3c47'	System	22 Sep 2020 19:02:27
User entered '22 Sep 2020 15:02'	System	22 Sep 2020 19:02:27

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 6'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-23T12:15:13', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'f7e117d9-77da-4360-97a0-eb8ff8fee4e2'	System	23 Sep 2020 16:15:35
User entered 'None (0)'	System	23 Sep 2020 16:15:35

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-23T12:15:14', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'f7e117d9-77da-4360-97a0-eb8ff8fee4e2'	System	23 Sep 2020 16:15:35
User entered 'None (0)'	System	23 Sep 2020 16:15:35

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-23T12:15:16', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'f7e117d9-77da-4360-97a0-eb8ff8fee4e2'	System	23 Sep 2020 16:15:35
User entered 'None (0)'	System	23 Sep 2020 16:15:35



US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-23T12:15:18', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'f7e117d9-77da-4360-97a0-eb8ff8fee4e2'	System	23 Sep 2020 16:15:35
User entered 'None (0)'	System	23 Sep 2020 16:15:35

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-23T12:15:19', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'f7e117d9-77da-4360-97a0-eb8ff8fee4e2'	System	23 Sep 2020 16:15:35
User entered 'None (0)'	System	23 Sep 2020 16:15:35

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-23T12:15:21', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'f7e117d9-77da-4360-97a0-eb8ff8fee4e2'	System	23 Sep 2020 16:15:35
User entered 'None (0)'	System	23 Sep 2020 16:15:35

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-23T12:15:23', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'f7e117d9-77da-4360-97a0-eb8ff8fee4e2'	System	23 Sep 2020 16:15:35
User entered 'No (N)'	System	23 Sep 2020 16:15:35

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-23T12:15:30', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'f7e117d9-77da-4360-97a0-eb8ff8fee4e2'	System	23 Sep 2020 16:15:35
User entered '23 Sep 2020 12:15'	System	23 Sep 2020 16:15:35

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 7'	System	18 Sep 2020 18:03:21



US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-24T14:14:45', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '4c2071ba-a755-41de-a2f4-6568404a58ba'	System	24 Sep 2020 18:15:02
User entered 'None (0)'	System	24 Sep 2020 18:15:02

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-24T14:14:46', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '4c2071ba-a755-41de-a2f4-6568404a58ba'	System	24 Sep 2020 18:15:02
User entered 'None (0)'	System	24 Sep 2020 18:15:02

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-24T14:14:47', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '4c2071ba-a755-41de-a2f4-6568404a58ba'	System	24 Sep 2020 18:15:02
User entered 'None (0)'	System	24 Sep 2020 18:15:02

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-24T14:14:48', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '4c2071ba-a755-41de-a2f4-6568404a58ba'	System	24 Sep 2020 18:15:02
User entered 'None (0)'	System	24 Sep 2020 18:15:02

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-24T14:14:50', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '4c2071ba-a755-41de-a2f4-6568404a58ba'	System	24 Sep 2020 18:15:02
User entered 'None (0)'	System	24 Sep 2020 18:15:02

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-24T14:14:52', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '4c2071ba-a755-41de-a2f4-6568404a58ba'	System	24 Sep 2020 18:15:02
User entered 'None (0)'	System	24 Sep 2020 18:15:02

US3522709

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-24T14:14:55', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '4c2071ba-a755-41de-a2f4-6568404a58ba'	System	24 Sep 2020 18:15:02
User entered 'No (N)'	System	24 Sep 2020 18:15:02

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-09-24T14:14:56', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '4c2071ba-a755-41de-a2f4-6568404a58ba'	System	24 Sep 2020 18:15:02
User entered '24 Sep 2020 14:14'	System	24 Sep 2020 18:15:02



**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:43:05

**US3522709**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:43:05

**US3522709**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:43:05

**US3522709**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
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) (b) (4), (b) (6)	28 Sep 2020 14:43:05

US3522709

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:43:11

**US3522709**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'I'	System	28 Sep 2020 14:43:11



**US3522709**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:27:07

**US3522709**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '2 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:27:07

US3522709

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	02 Oct 2020 19:51:30
reason for change: New Information	(b) (4), (b) (6)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	02 Oct 2020 15:27:07

US3522709

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Contact made after second attempt. No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure. No other vaccinations.' reason for change: New Information	(b) (4) (b) (4), (b) (6)	02 Oct 2020 19:51:30
User entered 'Voicemail left'	(b) (4), (b) (6)	02 Oct 2020 15:27:07

**US3522709**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:26:42

**US3522709**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'I'	System	02 Oct 2020 15:26:42

US3522709

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	09 Oct 2020 19:10:59
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	09 Oct 2020 19:04:58
User entered 'Yes (Y)'	Kristin Eis (b) (4)	09 Oct 2020 19:04:58
	(b) (4)	

**US3522709**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '09 Oct 2020'	Kristin Eis (b) (4)	09 Oct 2020 19:04:58



US3522709

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Kristin Eis (b) (4)	09 Oct 2020 19:10:59
User entered empty.	(b) (4)	
	Kristin Eis (b) (4)	09 Oct 2020 19:04:58
	(b) (4)	

US3522709

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
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	(b) (4) Kristin Eis (b) (4)	09 Oct 2020 19:10:59
User entered empty.	Kristin Eis (b) (4) (b) (4)	09 Oct 2020 19:04:58

**US3522709**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	Kristin Eis (b) (4)	09 Oct 2020 19:13:01

**US3522709**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'I'	System	09 Oct 2020 19:13:01

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	23 Oct 2020 18:09:55

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '23 Oct 2020'	(b) (4) Alayna Wilder (b) (4)	23 Oct 2020 18:09:55

US3522709

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Clinic (Clinic)'	Alayna Wilder (b) (4)	23 Oct 2020 18:09:55

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'VISIT2'	System	23 Oct 2020 18:09:55



**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Nov 2020 12:58:30

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 12:58:30

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 12:58:30

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '14:00'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 12:58:30

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered '23 Oct 2020 14:00'	System	10 Nov 2020 12:58:30

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	10 Nov 2020 12:58:30

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 12:58:30

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 12:58:30



US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '65'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 12:58:30

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'bpm'	System	10 Nov 2020 12:58:30

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '16'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 12:58:30

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'breaths/min'	System	10 Nov 2020 12:58:30

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '125'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 12:58:30

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'mmHg'	System	10 Nov 2020 12:58:30

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '61'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 12:58:30

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'mmHg'	System	10 Nov 2020 12:58:30



US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	23 Oct 2020 18:53:12

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:53:12

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:53:12

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '14:42'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:53:12

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered '23 Oct 2020 14:42'	System	23 Oct 2020 18:53:12

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:53:12

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:53:12

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:53:12



**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '68'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:53:12

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'bpm'	System	23 Oct 2020 18:53:12

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '16'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:53:12

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'breaths/min'	System	23 Oct 2020 18:53:12

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '103'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:53:12

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'mmHg'	System	23 Oct 2020 18:53:12

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '60'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:53:12

US3522709

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'mmHg'	System	23 Oct 2020 18:53:12



**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:06:13**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	23 Oct 2020 18:10:11

US3522709

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '23 Oct 2020'	(b) (4) Alayna Wilder (b) (4)	23 Oct 2020 18:10:11

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	23 Oct 2020 18:18:00

US3522709

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:13

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered empty.	(b) (4) Alayna Wilder (b) (4)	23 Oct 2020 18:18:00

US3522709

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered empty.	Alayna Wilder (b) (4)	23 Oct 2020 18:18:00

US3522709

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'MRNA-1273 OR PLACEBO'	System	23 Oct 2020 18:18:00

US3522709

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '23 Oct 2020'	(b) (4) Alayna Wilder (b) (4)	23 Oct 2020 18:18:00

US3522709

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '14:12'	(b) (4) Alayna Wilder (b) (4)	23 Oct 2020 18:18:00



**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered '23 Oct 2020 14:12'	System	23 Oct 2020 18:18:00

US3522709

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Left Arm (LEFT ARM)'	Alayna Wilder (b) (4)	23 Oct 2020 18:18:00

US3522709

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:13

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'ONCE'	System	23 Oct 2020 18:18:00

US3522709

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'INTRAMUSCULAR'	System	23 Oct 2020 18:18:00

US3522709

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Oct 2020 18:16:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 18:16:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Alayna Wilder (b) (4)	23 Oct 2020 18:16:15
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Oct 2020 18:10:27
User entered empty.	System	23 Oct 2020 18:10:27
	Alayna Wilder (b) (4)	23 Oct 2020 18:10:27
	(b) (4)	

US3522709

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Alayna Wilder (b) (4)	23 Oct 2020 18:16:15
User entered empty.	(b) (4)	
	Alayna Wilder (b) (4)	23 Oct 2020 18:10:27
	(b) (4)	

US3522709

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '14:05' reason for change: Data Entry Error	(b) (4)	
	Alayna Wilder (b) (4)	23 Oct 2020 18:16:15
User entered empty.	(b) (4)	
	Alayna Wilder (b) (4)	23 Oct 2020 18:10:27
	(b) (4)	

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered '23 Oct 2020 14:05'	System	23 Oct 2020 18:16:15
User entered empty.	System	23 Oct 2020 18:10:27



**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 08:06:13**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '23 Oct 2020'	(b) (4) Alayna Wilder (b) (4) (b) (4)	23 Oct 2020 18:16:37

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alayna Wilder (b) (4) (b) (4)	23 Oct 2020 18:16:37

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	23 Oct 2020 18:16:37

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '14:07'	(b) (4) Alayna Wilder (b) (4)	23 Oct 2020 18:16:37

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered '23 Oct 2020 14:07'	System	23 Oct 2020 18:16:37

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alayna Wilder (b) (4) (b) (4)	23 Oct 2020 18:16:37

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'No (N)'	(b) (4) Alayna Wilder (b) (4)	23 Oct 2020 18:16:37

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:06:13**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered empty.	(b) (4) Alayna Wilder (b) (4)	23 Oct 2020 18:16:37



**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered empty.	System	23 Oct 2020 18:16:37

US3522709

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	23 Oct 2020 18:16:45

**US3522709**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'I'	System	23 Oct 2020 18:16:45

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T14:46:54', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '121e6410-8cdc-435c-817f-84bd0762ec50'	System	23 Oct 2020 18:47:08
User entered 'Yes (Y)'	System	23 Oct 2020 18:47:08

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T14:46:57', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '121e6410-8cdc-435c-817f-84bd0762ec50'	System	23 Oct 2020 18:47:08
User entered '98.6'	System	23 Oct 2020 18:47:08

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T14:47:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '121e6410-8cdc-435c-817f-84bd0762ec50'	System	23 Oct 2020 18:47:08
User entered 'No (N)'	System	23 Oct 2020 18:47:08

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T14:47:03', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '121e6410-8cdc-435c-817f-84bd0762ec50'	System	23 Oct 2020 18:47:08
User entered '23 Oct 2020 14:47'	System	23 Oct 2020 18:47:08



US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '23 Oct 2020 14:32'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '23 Oct 2020 17:02'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T19:12:40', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '72ef53e2-ebd9-44fc-a609-1f306ea02c56'	System	23 Oct 2020 23:12:52
User entered 'Yes (Y)'	System	23 Oct 2020 23:12:52

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T19:12:43', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '72ef53e2-ebd9-44fc-a609-1f306ea02c56'	System	23 Oct 2020 23:12:52
User entered '96.3'	System	23 Oct 2020 23:12:52

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T19:12:45', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '72ef53e2-ebd9-44fc-a609-1f306ea02c56'	System	23 Oct 2020 23:12:52
User entered 'No (N)'	System	23 Oct 2020 23:12:52

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T19:12:47', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '72ef53e2-ebd9-44fc-a609-1f306ea02c56'	System	23 Oct 2020 23:12:52
User entered '23 Oct 2020 19:12'	System	23 Oct 2020 23:12:52

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '23 Oct 2020 17:57'	System	23 Oct 2020 18:18:00



US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 2'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-24T21:41:59', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '0f3287d0-81ee-4a1d-bb19-f48b639c3aaa'	System	25 Oct 2020 01:42:14
User entered 'Yes (Y)'	System	25 Oct 2020 01:42:14

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-24T21:42:06', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '0f3287d0-81ee-4a1d-bb19-f48b639c3aaa'	System	25 Oct 2020 01:42:14
User entered '97.5'	System	25 Oct 2020 01:42:14

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-24T21:42:08', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '0f3287d0-81ee-4a1d-bb19-f48b639c3aaa'	System	25 Oct 2020 01:42:14
User entered 'No (N)'	System	25 Oct 2020 01:42:14

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-24T21:42:11', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '0f3287d0-81ee-4a1d-bb19-f48b639c3aaa'	System	25 Oct 2020 01:42:14
User entered '24 Oct 2020 21:42'	System	25 Oct 2020 01:42:14

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:06:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 18:18:00



US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 3'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-25T17:04:37', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6e0e838e-18a3-4daa-a24e-2626bc5dc5e4'	System	25 Oct 2020 21:04:50
User entered 'Yes (Y)'	System	25 Oct 2020 21:04:50

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-25T17:04:39', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6e0e838e-18a3-4daa-a24e-2626bc5dc5e4'	System	25 Oct 2020 21:04:50
User entered '96.3'	System	25 Oct 2020 21:04:50

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-25T17:04:41', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6e0e838e-18a3-4daa-a24e-2626bc5dc5e4'	System	25 Oct 2020 21:04:50
User entered 'No (N)'	System	25 Oct 2020 21:04:50

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-25T17:04:43', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6e0e838e-18a3-4daa-a24e-2626bc5dc5e4'	System	25 Oct 2020 21:04:50
User entered '25 Oct 2020 17:04'	System	25 Oct 2020 21:04:50

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 4'	System	23 Oct 2020 18:18:00



US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T18:52:05', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '32cbf862-a86a-43d8-9290-63bde464bc2a'	System	26 Oct 2020 22:52:16
User entered 'Yes (Y)'	System	26 Oct 2020 22:52:16

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T18:52:08', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '32cbf862-a86a-43d8-9290-63bde464bc2a'	System	26 Oct 2020 22:52:16
User entered '96.6'	System	26 Oct 2020 22:52:16

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T18:52:10', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '32cbf862-a86a-43d8-9290-63bde464bc2a'	System	26 Oct 2020 22:52:16
User entered 'No (N)'	System	26 Oct 2020 22:52:16

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T18:52:12', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '32cbf862-a86a-43d8-9290-63bde464bc2a'	System	26 Oct 2020 22:52:16
User entered '26 Oct 2020 18:52'	System	26 Oct 2020 22:52:16

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:06:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 5'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-28T01:48:06', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '39d768b9-8eb3-498c-a575-9fd613c91af9'	System	28 Oct 2020 05:48:20
User entered 'Yes (Y)'	System	28 Oct 2020 05:48:20



US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-28T01:48:11', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '39d768b9-8eb3-498c-a575-9fd613c91af9'	System	28 Oct 2020 05:48:20
User entered '97.4'	System	28 Oct 2020 05:48:20

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-28T01:48:13', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '39d768b9-8eb3-498c-a575-9fd613c91af9'	System	28 Oct 2020 05:48:20
User entered 'No (N)'	System	28 Oct 2020 05:48:20

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-28T01:48:15', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '39d768b9-8eb3-498c-a575-9fd613c91af9'	System	28 Oct 2020 05:48:20
User entered '28 Oct 2020 01:48'	System	28 Oct 2020 05:48:20

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:06:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 6'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T02:23:24', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '0ca01f21-7d8c-4ee6-8db0-8d617ebb63f1'	System	29 Oct 2020 06:23:36
User entered 'Yes (Y)'	System	29 Oct 2020 06:23:36

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T02:23:28', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '0ca01f21-7d8c-4ee6-8db0-8d617ebb63f1'	System	29 Oct 2020 06:23:36
User entered '95.9'	System	29 Oct 2020 06:23:36



US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T02:23:30', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '0ca01f21-7d8c-4ee6-8db0-8d617ebb63f1'	System	29 Oct 2020 06:23:36
User entered 'No (N)'	System	29 Oct 2020 06:23:36

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T02:23:32', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '0ca01f21-7d8c-4ee6-8db0-8d617ebb63f1'	System	29 Oct 2020 06:23:36
User entered '29 Oct 2020 02:23'	System	29 Oct 2020 06:23:36

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 7'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T19:57:51', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '99207b82-e3d2-482c-9763-0cbdb61c0a79'	System	29 Oct 2020 23:57:59
User entered 'Yes (Y)'	System	29 Oct 2020 23:57:59

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T19:57:53', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '99207b82-e3d2-482c-9763-0cbdb61c0a79'	System	29 Oct 2020 23:57:59
User entered '96.2'	System	29 Oct 2020 23:57:59

US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T19:57:55', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '99207b82-e3d2-482c-9763-0cbdb61c0a79'	System	29 Oct 2020 23:57:59
User entered 'No (N)'	System	29 Oct 2020 23:57:59



US3522709

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:06:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T19:57:56', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '99207b82-e3d2-482c-9763-0cbdb61c0a79'	System	29 Oct 2020 23:57:59
User entered '29 Oct 2020 19:57'	System	29 Oct 2020 23:57:59

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T14:47:07', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '23043cd3-584c-4339-a3ee-cc35a221ba5b'	System	23 Oct 2020 18:47:20
User entered 'None (1)'	System	23 Oct 2020 18:47:20

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T14:47:09', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '23043cd3-584c-4339-a3ee-cc35a221ba5b'	System	23 Oct 2020 18:47:20
User entered 'No (N)'	System	23 Oct 2020 18:47:20

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T14:47:10', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '23043cd3-584c-4339-a3ee-cc35a221ba5b'	System	23 Oct 2020 18:47:20
User entered 'No (N)'	System	23 Oct 2020 18:47:20

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T14:47:12', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '23043cd3-584c-4339-a3ee-cc35a221ba5b'	System	23 Oct 2020 18:47:20
User entered 'None (1)'	System	23 Oct 2020 18:47:20



**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T14:47:15', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '23043cd3-584c-4339-a3ee-cc35a221ba5b'	System	23 Oct 2020 18:47:20
User entered '23 Oct 2020 14:47'	System	23 Oct 2020 18:47:20

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '23 Oct 2020 14:32'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '23 Oct 2020 17:02'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T19:12:53', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '9c461c9f-45de-4cbc-907a-4740fcf82e32'	System	23 Oct 2020 23:13:03
User entered 'None (1)'	System	23 Oct 2020 23:13:03

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T19:12:54', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '9c461c9f-45de-4cbc-907a-4740fcf82e32'	System	23 Oct 2020 23:13:03
User entered 'No (N)'	System	23 Oct 2020 23:13:03

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T19:12:56', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '9c461c9f-45de-4cbc-907a-4740fcf82e32'	System	23 Oct 2020 23:13:03
User entered 'No (N)'	System	23 Oct 2020 23:13:03

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T19:12:59', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '9c461c9f-45de-4cbc-907a-4740fcf82e32'	System	23 Oct 2020 23:13:03
User entered 'None (1)'	System	23 Oct 2020 23:13:03



**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T19:13:01', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '9c461c9f-45de-4cbc-907a-4740fcf82e32'	System	23 Oct 2020 23:13:03
User entered '23 Oct 2020 19:13'	System	23 Oct 2020 23:13:03

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '23 Oct 2020 17:57'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 2'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-24T21:42:24', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '1d9c5e53-0abe-4de8-ba42-6ce796b72568'	System	25 Oct 2020 01:42:35
User entered 'None (1)'	System	25 Oct 2020 01:42:35

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-24T21:42:25', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '1d9c5e53-0abe-4de8-ba42-6ce796b72568'	System	25 Oct 2020 01:42:35
User entered 'No (N)'	System	25 Oct 2020 01:42:35

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-24T21:42:27', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '1d9c5e53-0abe-4de8-ba42-6ce796b72568'	System	25 Oct 2020 01:42:35
User entered 'No (N)'	System	25 Oct 2020 01:42:35

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-24T21:42:28', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '1d9c5e53-0abe-4de8-ba42-6ce796b72568'	System	25 Oct 2020 01:42:35
User entered 'None (1)'	System	25 Oct 2020 01:42:35



**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-24T21:42:31', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '1d9c5e53-0abe-4de8-ba42-6ce796b72568'	System	25 Oct 2020 01:42:35
User entered '24 Oct 2020 21:42'	System	25 Oct 2020 01:42:35

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 3'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-25T17:04:46', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '8d9fd25a-06fb-4776-bbdd-42bdbdf203f6'	System	25 Oct 2020 21:05:06
User entered 'None (1)'	System	25 Oct 2020 21:05:06

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-25T17:04:48', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '8d9fd25a-06fb-4776-bbdd-42bdbdf203f6'	System	25 Oct 2020 21:05:06
User entered 'No (N)'	System	25 Oct 2020 21:05:06

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-25T17:04:53', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '8d9fd25a-06fb-4776-bbdd-42bdbdf203f6'	System	25 Oct 2020 21:05:06
User entered 'No (N)'	System	25 Oct 2020 21:05:06

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-25T17:04:54', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '8d9fd25a-06fb-4776-bbdd-42bdbdf203f6'	System	25 Oct 2020 21:05:06
User entered 'None (1)'	System	25 Oct 2020 21:05:06



**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-25T17:04:59', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '8d9fd25a-06fb-4776-bbdd-42bdbdf203f6'	System	25 Oct 2020 21:05:06
User entered '25 Oct 2020 17:04'	System	25 Oct 2020 21:05:06

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 4'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T18:52:14', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c8f53cde-7398-4572-af3f-3b2bad7ff2d9'	System	26 Oct 2020 22:52:24
User entered 'None (1)'	System	26 Oct 2020 22:52:24

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T18:52:16', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c8f53cde-7398-4572-af3f-3b2bad7ff2d9'	System	26 Oct 2020 22:52:24
User entered 'No (N)'	System	26 Oct 2020 22:52:24

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T18:52:17', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c8f53cde-7398-4572-af3f-3b2bad7ff2d9'	System	26 Oct 2020 22:52:24
User entered 'No (N)'	System	26 Oct 2020 22:52:24

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T18:52:18', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c8f53cde-7398-4572-af3f-3b2bad7ff2d9'	System	26 Oct 2020 22:52:24
User entered 'None (1)'	System	26 Oct 2020 22:52:24



**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T18:52:20', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c8f53cde-7398-4572-af3f-3b2bad7ff2d9'	System	26 Oct 2020 22:52:24
User entered '26 Oct 2020 18:52'	System	26 Oct 2020 22:52:24

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 5'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-28T01:48:20', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'e9ede5a2-d981-4ac1-879b-a38d6bdb1583'	System	28 Oct 2020 05:48:31
User entered 'None (1)'	System	28 Oct 2020 05:48:31

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-28T01:48:21', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'e9ede5a2-d981-4ac1-879b-a38d6bdb1583'	System	28 Oct 2020 05:48:31
User entered 'No (N)'	System	28 Oct 2020 05:48:31

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-28T01:48:23', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'e9ede5a2-d981-4ac1-879b-a38d6bdb1583'	System	28 Oct 2020 05:48:31
User entered 'No (N)'	System	28 Oct 2020 05:48:31

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-28T01:48:24', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'e9ede5a2-d981-4ac1-879b-a38d6bdb1583'	System	28 Oct 2020 05:48:31
User entered 'None (1)'	System	28 Oct 2020 05:48:31



**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-28T01:48:26', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'e9ede5a2-d981-4ac1-879b-a38d6bdb1583'	System	28 Oct 2020 05:48:31
User entered '28 Oct 2020 01:48'	System	28 Oct 2020 05:48:31

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 6'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T02:23:35', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '86812e2e-28e3-4438-b4ec-98664ef6e82b'	System	29 Oct 2020 06:23:47
User entered 'None (1)'	System	29 Oct 2020 06:23:47

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T02:23:36', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '86812e2e-28e3-4438-b4ec-98664ef6e82b'	System	29 Oct 2020 06:23:47
User entered 'No (N)'	System	29 Oct 2020 06:23:47

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T02:23:38', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '86812e2e-28e3-4438-b4ec-98664ef6e82b'	System	29 Oct 2020 06:23:47
User entered 'No (N)'	System	29 Oct 2020 06:23:47

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T02:23:39', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '86812e2e-28e3-4438-b4ec-98664ef6e82b'	System	29 Oct 2020 06:23:47
User entered 'None (1)'	System	29 Oct 2020 06:23:47



**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T02:23:42', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '86812e2e-28e3-4438-b4ec-98664ef6e82b'	System	29 Oct 2020 06:23:47
User entered '29 Oct 2020 02:23'	System	29 Oct 2020 06:23:47

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 7'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T19:57:59', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b1220337-9b3e-4ef1-b88f-a46565fd7f1b'	System	29 Oct 2020 23:58:09
User entered 'None (1)'	System	29 Oct 2020 23:58:09

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T19:58:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b1220337-9b3e-4ef1-b88f-a46565fd7f1b'	System	29 Oct 2020 23:58:09
User entered 'No (N)'	System	29 Oct 2020 23:58:09

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T19:58:01', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b1220337-9b3e-4ef1-b88f-a46565fd7f1b'	System	29 Oct 2020 23:58:09
User entered 'No (N)'	System	29 Oct 2020 23:58:09

US3522709

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T19:58:02', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b1220337-9b3e-4ef1-b88f-a46565fd7f1b'	System	29 Oct 2020 23:58:09
User entered 'None (1)'	System	29 Oct 2020 23:58:09



**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T19:58:04', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b1220337-9b3e-4ef1-b88f-a46565fd7f1b'	System	29 Oct 2020 23:58:09
User entered '29 Oct 2020 19:58'	System	29 Oct 2020 23:58:09

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T14:47:18', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6c5c1acc-6398-4304-b315-13f0f3517b3c'	System	23 Oct 2020 18:47:34
User entered 'None (0)'	System	23 Oct 2020 18:47:34

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T14:47:19', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6c5c1acc-6398-4304-b315-13f0f3517b3c'	System	23 Oct 2020 18:47:34
User entered 'None (0)'	System	23 Oct 2020 18:47:34

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T14:47:20', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6c5c1acc-6398-4304-b315-13f0f3517b3c'	System	23 Oct 2020 18:47:34
User entered 'None (0)'	System	23 Oct 2020 18:47:34

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T14:47:22', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6c5c1acc-6398-4304-b315-13f0f3517b3c'	System	23 Oct 2020 18:47:34
User entered 'None (0)'	System	23 Oct 2020 18:47:34



US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T14:47:23', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6c5c1acc-6398-4304-b315-13f0f3517b3c'	System	23 Oct 2020 18:47:34
User entered 'None (0)'	System	23 Oct 2020 18:47:34

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T14:47:25', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6c5c1acc-6398-4304-b315-13f0f3517b3c'	System	23 Oct 2020 18:47:34
User entered 'None (0)'	System	23 Oct 2020 18:47:34

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T14:47:27', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6c5c1acc-6398-4304-b315-13f0f3517b3c'	System	23 Oct 2020 18:47:34
User entered 'No (N)'	System	23 Oct 2020 18:47:34

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T14:47:28', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6c5c1acc-6398-4304-b315-13f0f3517b3c'	System	23 Oct 2020 18:47:34
User entered '23 Oct 2020 14:47'	System	23 Oct 2020 18:47:34

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:06:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '23 Oct 2020 14:32'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '23 Oct 2020 17:02'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T19:13:23', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b2575535-0e6e-4030-bdb5-25cbff9f5b4f'	System	23 Oct 2020 23:13:40
User entered 'None (0)'	System	23 Oct 2020 23:13:40



US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T19:13:25', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b2575535-0e6e-4030-bdb5-25cbff9f5b4f'	System	23 Oct 2020 23:13:40
User entered 'None (0)'	System	23 Oct 2020 23:13:40

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T19:13:26', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b2575535-0e6e-4030-bdb5-25cbff9f5b4f'	System	23 Oct 2020 23:13:40
User entered 'None (0)'	System	23 Oct 2020 23:13:40

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T19:13:28', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b2575535-0e6e-4030-bdb5-25cbff9f5b4f'	System	23 Oct 2020 23:13:40
User entered 'None (0)'	System	23 Oct 2020 23:13:40

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T19:13:29', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b2575535-0e6e-4030-bdb5-25cbff9f5b4f'	System	23 Oct 2020 23:13:40
User entered 'None (0)'	System	23 Oct 2020 23:13:40

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T19:13:33', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b2575535-0e6e-4030-bdb5-25cbff9f5b4f'	System	23 Oct 2020 23:13:40
User entered 'None (0)'	System	23 Oct 2020 23:13:40

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T19:13:35', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b2575535-0e6e-4030-bdb5-25cbff9f5b4f'	System	23 Oct 2020 23:13:40
User entered 'No (N)'	System	23 Oct 2020 23:13:40

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-23T19:13:37', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b2575535-0e6e-4030-bdb5-25cbff9f5b4f'	System	23 Oct 2020 23:13:40
User entered '23 Oct 2020 19:13'	System	23 Oct 2020 23:13:40

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '23 Oct 2020 17:57'	System	23 Oct 2020 18:18:00



**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 2'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-24T21:42:34', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '87176a74-3f8d-41d8-9dab-e838847a99b6'	System	25 Oct 2020 01:42:52
User entered 'None (0)'	System	25 Oct 2020 01:42:52

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-24T21:42:35', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '87176a74-3f8d-41d8-9dab-e838847a99b6'	System	25 Oct 2020 01:42:52
User entered 'None (0)'	System	25 Oct 2020 01:42:52

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-24T21:42:37', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '87176a74-3f8d-41d8-9dab-e838847a99b6'	System	25 Oct 2020 01:42:52
User entered 'None (0)'	System	25 Oct 2020 01:42:52

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-24T21:42:38', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '87176a74-3f8d-41d8-9dab-e838847a99b6'	System	25 Oct 2020 01:42:52
User entered 'None (0)'	System	25 Oct 2020 01:42:52

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-24T21:42:39', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '87176a74-3f8d-41d8-9dab-e838847a99b6'	System	25 Oct 2020 01:42:52
User entered 'None (0)'	System	25 Oct 2020 01:42:52

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-24T21:42:41', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '87176a74-3f8d-41d8-9dab-e838847a99b6'	System	25 Oct 2020 01:42:52
User entered 'None (0)'	System	25 Oct 2020 01:42:52



US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-24T21:42:43', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '87176a74-3f8d-41d8-9dab-e838847a99b6'	System	25 Oct 2020 01:42:52
User entered 'No (N)'	System	25 Oct 2020 01:42:52

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-24T21:42:49', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '87176a74-3f8d-41d8-9dab-e838847a99b6'	System	25 Oct 2020 01:42:52
User entered '24 Oct 2020 21:42'	System	25 Oct 2020 01:42:52

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 3'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-25T17:05:02', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '56193e2f-5ce5-4640-8187-f2efb8817bb6'	System	26 Oct 2020 04:20:49
User entered 'None (0)'	System	26 Oct 2020 04:20:49

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-25T17:05:03', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '56193e2f-5ce5-4640-8187-f2efb8817bb6'	System	26 Oct 2020 04:20:49
User entered 'None (0)'	System	26 Oct 2020 04:20:49

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-25T17:05:04', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '56193e2f-5ce5-4640-8187-f2efb8817bb6'	System	26 Oct 2020 04:20:49
User entered 'None (0)'	System	26 Oct 2020 04:20:49



US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-25T17:05:05', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '56193e2f-5ce5-4640-8187-f2efb8817bb6'	System	26 Oct 2020 04:20:49
User entered 'None (0)'	System	26 Oct 2020 04:20:49

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-25T17:05:06', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '56193e2f-5ce5-4640-8187-f2efb8817bb6'	System	26 Oct 2020 04:20:49
User entered 'None (0)'	System	26 Oct 2020 04:20:49

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-25T17:05:07', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '56193e2f-5ce5-4640-8187-f2efb8817bb6'	System	26 Oct 2020 04:20:49
User entered 'None (0)'	System	26 Oct 2020 04:20:49

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T00:20:37', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '56193e2f-5ce5-4640-8187-f2efb8817bb6'	System	26 Oct 2020 04:20:49
User entered 'No (N)'	System	26 Oct 2020 04:20:49

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T00:20:45', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '56193e2f-5ce5-4640-8187-f2efb8817bb6'	System	26 Oct 2020 04:20:49
User entered '26 Oct 2020 00:20'	System	26 Oct 2020 04:20:49

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 4'	System	23 Oct 2020 18:18:00



US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T18:52:23', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'da75ff5b-8378-4b73-b601-90caaf6d6a85'	System	26 Oct 2020 22:52:40
User entered 'None (0)'	System	26 Oct 2020 22:52:40

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T18:52:24', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'da75ff5b-8378-4b73-b601-90caaf6d6a85'	System	26 Oct 2020 22:52:40
User entered 'None (0)'	System	26 Oct 2020 22:52:40

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T18:52:26', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'da75ff5b-8378-4b73-b601-90caaf6d6a85'	System	26 Oct 2020 22:52:40
User entered 'None (0)'	System	26 Oct 2020 22:52:40

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T18:52:27', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'da75ff5b-8378-4b73-b601-90caaf6d6a85'	System	26 Oct 2020 22:52:40
User entered 'None (0)'	System	26 Oct 2020 22:52:40

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T18:52:28', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'da75ff5b-8378-4b73-b601-90caaf6d6a85'	System	26 Oct 2020 22:52:40
User entered 'None (0)'	System	26 Oct 2020 22:52:40

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T18:52:29', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'da75ff5b-8378-4b73-b601-90caaf6d6a85'	System	26 Oct 2020 22:52:40
User entered 'None (0)'	System	26 Oct 2020 22:52:40

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T18:52:30', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'da75ff5b-8378-4b73-b601-90caaf6d6a85'	System	26 Oct 2020 22:52:40
User entered 'No (N)'	System	26 Oct 2020 22:52:40

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-26T18:52:33', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'da75ff5b-8378-4b73-b601-90caaf6d6a85'	System	26 Oct 2020 22:52:40
User entered '26 Oct 2020 18:52'	System	26 Oct 2020 22:52:40



**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 5'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-28T01:48:30', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '769f810d-f9db-472c-908e-32f6b2ca2518'	System	28 Oct 2020 05:48:44
User entered 'None (0)'	System	28 Oct 2020 05:48:44

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-28T01:48:32', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '769f810d-f9db-472c-908e-32f6b2ca2518'	System	28 Oct 2020 05:48:44
User entered 'None (0)'	System	28 Oct 2020 05:48:44

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-28T01:48:33', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '769f810d-f9db-472c-908e-32f6b2ca2518'	System	28 Oct 2020 05:48:44
User entered 'None (0)'	System	28 Oct 2020 05:48:44

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-28T01:48:34', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '769f810d-f9db-472c-908e-32f6b2ca2518'	System	28 Oct 2020 05:48:44
User entered 'None (0)'	System	28 Oct 2020 05:48:44

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-28T01:48:36', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '769f810d-f9db-472c-908e-32f6b2ca2518'	System	28 Oct 2020 05:48:44
User entered 'None (0)'	System	28 Oct 2020 05:48:44



US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-28T01:48:37', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '769f810d-f9db-472c-908e-32f6b2ca2518'	System	28 Oct 2020 05:48:44
User entered 'None (0)'	System	28 Oct 2020 05:48:44

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-28T01:48:38', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '769f810d-f9db-472c-908e-32f6b2ca2518'	System	28 Oct 2020 05:48:44
User entered 'No (N)'	System	28 Oct 2020 05:48:44

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-28T01:48:40', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '769f810d-f9db-472c-908e-32f6b2ca2518'	System	28 Oct 2020 05:48:44
User entered '28 Oct 2020 01:48'	System	28 Oct 2020 05:48:44

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 6'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T02:23:45', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '97eb9f37-db5a-4475-adae-466f959b3d25'	System	29 Oct 2020 06:23:57
User entered 'None (0)'	System	29 Oct 2020 06:23:57

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T02:23:46', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '97eb9f37-db5a-4475-adae-466f959b3d25'	System	29 Oct 2020 06:23:57
User entered 'None (0)'	System	29 Oct 2020 06:23:57



US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T02:23:47', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '97eb9f37-db5a-4475-adae-466f959b3d25'	System	29 Oct 2020 06:23:57
User entered 'None (0)'	System	29 Oct 2020 06:23:57

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T02:23:48', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '97eb9f37-db5a-4475-adae-466f959b3d25'	System	29 Oct 2020 06:23:57
User entered 'None (0)'	System	29 Oct 2020 06:23:57

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T02:23:50', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '97eb9f37-db5a-4475-adae-466f959b3d25'	System	29 Oct 2020 06:23:57
User entered 'None (0)'	System	29 Oct 2020 06:23:57

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T02:23:51', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '97eb9f37-db5a-4475-adae-466f959b3d25'	System	29 Oct 2020 06:23:57
User entered 'None (0)'	System	29 Oct 2020 06:23:57

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T02:23:52', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '97eb9f37-db5a-4475-adae-466f959b3d25'	System	29 Oct 2020 06:23:57
User entered 'No (N)'	System	29 Oct 2020 06:23:57

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T02:23:54', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '97eb9f37-db5a-4475-adae-466f959b3d25'	System	29 Oct 2020 06:23:57
User entered '29 Oct 2020 02:23'	System	29 Oct 2020 06:23:57

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 18:18:00



**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
Data entry locked.	System	23 Oct 2020 18:18:00
User entered 'Day 7'	System	23 Oct 2020 18:18:00

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T19:58:09', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'ad02acd0-e894-41f1-b669-493b4364af44'	System	29 Oct 2020 23:58:50
User entered 'None (0)'	System	29 Oct 2020 23:58:50

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T19:58:10', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'ad02acd0-e894-41f1-b669-493b4364af44'	System	29 Oct 2020 23:58:50
User entered 'None (0)'	System	29 Oct 2020 23:58:50

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T19:58:11', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'ad02acd0-e894-41f1-b669-493b4364af44'	System	29 Oct 2020 23:58:50
User entered 'None (0)'	System	29 Oct 2020 23:58:50

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T19:58:12', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'ad02acd0-e894-41f1-b669-493b4364af44'	System	29 Oct 2020 23:58:50
User entered 'None (0)'	System	29 Oct 2020 23:58:50

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T19:58:13', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'ad02acd0-e894-41f1-b669-493b4364af44'	System	29 Oct 2020 23:58:50
User entered 'None (0)'	System	29 Oct 2020 23:58:50

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T19:58:14', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'ad02acd0-e894-41f1-b669-493b4364af44'	System	29 Oct 2020 23:58:50
User entered 'None (0)'	System	29 Oct 2020 23:58:50

US3522709

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:06:13

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 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T19:58:16', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'ad02acd0-e894-41f1-b669-493b4364af44'	System	29 Oct 2020 23:58:50
User entered 'No (N)'	System	29 Oct 2020 23:58:50



**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (375a3f1b35632790)', Time: '2020-10-29T19:58:43', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'ad02acd0-e894-41f1-b669-493b4364af44'	System	29 Oct 2020 23:58:50
User entered '29 Oct 2020 19:58'	System	29 Oct 2020 23:58:50

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:06:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:47:26
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 18:18:00

**US3522709**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:36:32

US3522709

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 12:29:14
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'multiple contact attempts; see audit history ' (Site from System).	Yaman Ahmed (b) (4) (b) (4)	03 Nov 2020 22:15:54
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 Nov 2020 22:13:59
User entered '3 Nov 2020' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	03 Nov 2020 22:13:59
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 17:36:32

US3522709

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: New Information	Yaman Ahmed (b) (4)	03 Nov 2020 22:13:59
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	30 Oct 2020 17:36:32

US3522709

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'LOWER TEMPS IN E-DIARY DUE TO WORKPLACE THERMOMETER WHICH USUALLY REGISTERED LOW TEMPS.NO AE REPORTED, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, OR COVID-19 EXPOSURE'	Yaman Ahmed (b) (4)	03 Nov 2020 22:15:43
reason for change: New Information		
User entered 'Explains that the lower temperatures in e-diary are due to using a workplace thermometer which usually registered low temperatures. Otherwise, no AE reported, no new illness or hospital visits; no changes in health status, medications, or Covid-19 exposure risk' (non-conformant).	Yaman Ahmed (b) (4)	03 Nov 2020 22:13:59
User entered 'call attempted; VM left with return contact information'	(b) (4), (b) (6)	30 Oct 2020 17:36:32

US3522709

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	03 Nov 2020 22:15:59



**US3522709**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'I'	System	03 Nov 2020 22:15:59

**US3522709**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:30:14

**US3522709**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '6 Nov 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:30:14

**US3522709**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:30:14

**US3522709**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'call attempted; VM left with return contact information.'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:30:14

**US3522709**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:56:56

**US3522709**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'I'	System	13 Nov 2020 14:56:56

**US3522709**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:57:06



**US3522709**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:57:06

**US3522709**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:57:06

US3522709

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
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)	13 Nov 2020 14:57:06

US3522709

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 19:32:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 15:00:58

**US3522709**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'I'	System	13 Nov 2020 15:00:58

US3522709

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:12:08

**US3522709**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:12:08

**US3522709**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:12:08



**US3522709**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'VISIT3'	System	23 Nov 2020 19:12:08

US3522709

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:13:34

US3522709

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:13:34

**US3522709**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered '13:58'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:13:34

**US3522709**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered '23 Nov 2020 13:58'	System	23 Nov 2020 19:13:34

**US3522709**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered '97.3' F	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:13:34

US3522709

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:13:34

**US3522709**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:13:34



**US3522709**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered '85'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:13:34

**US3522709**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'bpm'	System	23 Nov 2020 19:13:34

US3522709

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered '16'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:13:34

US3522709

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'breaths/min'	System	23 Nov 2020 19:13:34

US3522709

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered '134'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:13:34

**US3522709**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'mmHg'	System	23 Nov 2020 19:13:34

US3522709

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered '74'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:13:34

**US3522709**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'mmHg'	System	23 Nov 2020 19:13:34



**US3522709**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46

**US3522709**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46

US3522709

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:13:40

US3522709

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:13:40

**US3522709**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:13:57

US3522709

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:13:57

**US3522709**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered '14:00'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:13:57

**US3522709**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered '23 Nov 2020 14:00'	System	23 Nov 2020 19:13:57



**US3522709**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	12 Feb 2021 22:16:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:14:01

**US3522709**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'I'	System	23 Nov 2020 19:14:01

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45
Data entry locked.	System	18 Sep 2020 18:03:21
User entered 'Day 64'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45
Data entry locked.	System	18 Sep 2020 18:03:21
User entered '18 Nov 2020 00:01'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:35:45
Data entry locked.	System	18 Sep 2020 18:03:21
User entered '22 Nov 2020 23:59'	System	18 Sep 2020 18:03:21

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (24961d39c22dac78)', Time: '2020-11-23T14:04:16', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b4b529d7-f24d-410c-8221-cb6f83aa760c'	System	23 Nov 2020 19:04:31
User entered 'No (N)'	System	23 Nov 2020 19:04:31



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Have you been exposed to someone with 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 (24961d39c22dac78)', Time: '2020-11-23T14:04:25', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b4b529d7-f24d-410c-8221-cb6f83aa760c'	System	23 Nov 2020 19:04:31
User entered 'No (N)'	System	23 Nov 2020 19:04:31

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24961d39c22dac78)', Time: '2020-11-23T14:04:27', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b4b529d7-f24d-410c-8221-cb6f83aa760c'	System	23 Nov 2020 19:04:31
User entered '23 Nov 2020 14:04:27'	System	23 Nov 2020 19:04:31

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (24961d39c22dac78)', Time: '2020-12-03T12:16:23', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '4af94131-1f7a-4179-85a5-3290d5f05b0f'	System	03 Dec 2020 17:16:33
User entered 'No (N)'	System	03 Dec 2020 17:16:33

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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 (24961d39c22dac78)', Time: '2020-12-03T12:16:25', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '4af94131-1f7a-4179-85a5-3290d5f05b0f'	System	03 Dec 2020 17:16:33
User entered 'No (N)'	System	03 Dec 2020 17:16:33

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24961d39c22dac78)', Time: '2020-12-03T12:16:27', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '4af94131-1f7a-4179-85a5-3290d5f05b0f' User entered '03 Dec 2020 12:16:27'	System	03 Dec 2020 17:16:33



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (24961d39c22dac78)', Time: '2020-12-06T10:58:12', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '894a96e4-b615-405b-a7c1-8fa10866d790'	System	06 Dec 2020 15:58:22
User entered 'No (N)'	System	06 Dec 2020 15:58:22

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Have you been exposed to someone with 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 (24961d39c22dac78)', Time: '2020-12-06T10:58:15', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '894a96e4-b615-405b-a7c1-8fa10866d790'	System	06 Dec 2020 15:58:22
User entered 'No (N)'	System	06 Dec 2020 15:58:22

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24961d39c22dac78)', Time: '2020-12-06T10:58:17', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '894a96e4-b615-405b-a7c1-8fa10866d790'	System	06 Dec 2020 15:58:22
User entered '06 Dec 2020 10:58:17'	System	06 Dec 2020 15:58:22

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (24961d39c22dac78)', Time: '2020-12-13T02:19:15', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'f4d16532-44f1-438d-9b40-14055d963285'	System	13 Dec 2020 07:19:19
User entered 'No (N)'	System	13 Dec 2020 07:19:19

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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 (24961d39c22dac78)', Time: '2020-12-13T02:19:16', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'f4d16532-44f1-438d-9b40-14055d963285'	System	13 Dec 2020 07:19:19
User entered 'No (N)'	System	13 Dec 2020 07:19:19

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24961d39c22dac78)', Time: '2020-12-13T02:19:18', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'f4d16532-44f1-438d-9b40-14055d963285'	System	13 Dec 2020 07:19:19
User entered '13 Dec 2020 02:19:18'	System	13 Dec 2020 07:19:19

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (24961d39c22dac78)', Time: '2020-12-20T00:09:27', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'dbf0196c-2dcB-4797-833f-92d218fe9337'	System	20 Dec 2020 05:09:35
User entered 'No (N)'	System	20 Dec 2020 05:09:35



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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 (24961d39c22dac78)', Time: '2020-12-20T00:09:29', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'dbf0196c-2dcB-4797-833f-92d218fe9337'	System	20 Dec 2020 05:09:35
User entered 'No (N)'	System	20 Dec 2020 05:09:35

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24961d39c22dac78)', Time: '2020-12-20T00:09:31', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'dbf0196c-2dcB-4797-833f-92d218fe9337'	System	20 Dec 2020 05:09:35
User entered '20 Dec 2020 00:09:31'	System	20 Dec 2020 05:09:35

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (24961d39c22dac78)', Time: '2020-12-27T07:11:15', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '211ca225-c44f-468d-8792-fd5d7210442c'	System	27 Dec 2020 12:11:26
User entered 'No (N)'	System	27 Dec 2020 12:11:26

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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 (24961d39c22dac78)', Time: '2020-12-27T07:11:20', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '211ca225-c44f-468d-8792-fd5d7210442c'	System	27 Dec 2020 12:11:26
User entered 'No (N)'	System	27 Dec 2020 12:11:26

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24961d39c22dac78)', Time: '2020-12-27T07:11:23', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '211ca225-c44f-468d-8792-fd5d7210442c' User entered '27 Dec 2020 07:11:23'	System	27 Dec 2020 12:11:26
	System	27 Dec 2020 12:11:26



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (24961d39c22dac78)', Time: '2021-01-03T01:01:07', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '1027ccea-64bb-4708-9439-876729458227'	System	03 Jan 2021 06:01:19
User entered 'No (N)'	System	03 Jan 2021 06:01:19

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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 (24961d39c22dac78)', Time: '2021-01-03T01:01:09', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '1027ccea-64bb-4708-9439-876729458227'	System	03 Jan 2021 06:01:19
User entered 'No (N)'	System	03 Jan 2021 06:01:19

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24961d39c22dac78)', Time: '2021-01-03T01:01:10', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '1027ccea-64bb-4708-9439-876729458227'	System	03 Jan 2021 06:01:19
User entered '03 Jan 2021 01:01:10'	System	03 Jan 2021 06:01:19

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (24961d39c22dac78)', Time: '2021-01-14T11:56:32', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '5eec6291-eb91-49c5-9af1-83f193028cb0'	System	14 Jan 2021 16:56:39
User entered 'No (N)'	System	14 Jan 2021 16:56:39

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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 (24961d39c22dac78)', Time: '2021-01-14T11:56:35', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '5eec6291-eb91-49c5-9af1-83f193028cb0'	System	14 Jan 2021 16:56:39
User entered 'No (N)'	System	14 Jan 2021 16:56:39

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24961d39c22dac78)', Time: '2021-01-14T11:56:37', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '5eec6291-eb91-49c5-9af1-83f193028cb0'	System	14 Jan 2021 16:56:39
User entered '14 Jan 2021 11:56:37'	System	14 Jan 2021 16:56:39

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (24961d39c22dac78)', Time: '2021-01-17T00:12:08', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '95927740-f399-4a6e-8fc4-ad7f64102d17'	System	17 Jan 2021 05:12:15
User entered 'No (N)'	System	17 Jan 2021 05:12:15



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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 (24961d39c22dac78)', Time: '2021-01-17T00:12:10', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '95927740-f399-4a6e-8fc4-ad7f64102d17'	System	17 Jan 2021 05:12:15
User entered 'No (N)'	System	17 Jan 2021 05:12:15

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24961d39c22dac78)', Time: '2021-01-17T00:12:11', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '95927740-f399-4a6e-8fc4-ad7f64102d17'	System	17 Jan 2021 05:12:15
User entered '17 Jan 2021 00:12:11'	System	17 Jan 2021 05:12:15

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (24961d39c22dac78)', Time: '2021-01-24T00:30:37', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c905d8bf-2eb4-497f-a5e8-e2dd78d0cf25'	System	24 Jan 2021 05:30:43
User entered 'No (N)'	System	24 Jan 2021 05:30:43

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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 (24961d39c22dac78)', Time: '2021-01-24T00:30:39', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c905d8bf-2eb4-497f-a5e8-e2dd78d0cf25'	System	24 Jan 2021 05:30:43
User entered 'No (N)'	System	24 Jan 2021 05:30:43

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24961d39c22dac78)', Time: '2021-01-24T00:30:40', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'c905d8bf-2eb4-497f-a5e8-e2dd78d0cf25'	System	24 Jan 2021 05:30:43
User entered '24 Jan 2021 00:30:40'	System	24 Jan 2021 05:30:43



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (24961d39c22dac78)', Time: '2021-02-04T09:38:16', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '61152fe3-78e5-4362-be5f-4179b9d95918'	System	04 Feb 2021 14:38:25
User entered 'No (N)'	System	04 Feb 2021 14:38:25

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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 (24961d39c22dac78)', Time: '2021-02-04T09:38:18', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '61152fe3-78e5-4362-be5f-4179b9d95918'	System	04 Feb 2021 14:38:25
User entered 'No (N)'	System	04 Feb 2021 14:38:25

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24961d39c22dac78)', Time: '2021-02-04T09:38:20', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '61152fe3-78e5-4362-be5f-4179b9d95918'	System	04 Feb 2021 14:38:25
User entered '04 Feb 2021 09:38:20'	System	04 Feb 2021 14:38:25

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (24961d39c22dac78)', Time: '2021-02-07T00:46:56', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '4b7775ec-ad18-44f1-8940-a4337ec8687f'	System	07 Feb 2021 05:47:04
User entered 'No (N)'	System	07 Feb 2021 05:47:04

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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 (24961d39c22dac78)', Time: '2021-02-07T00:46:57', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '4b7775ec-ad18-44f1-8940-a4337ec8687f'	System	07 Feb 2021 05:47:04
User entered 'No (N)'	System	07 Feb 2021 05:47:04

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24961d39c22dac78)', Time: '2021-02-07T00:46:59', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '4b7775ec-ad18-44f1-8940-a4337ec8687f'	System	07 Feb 2021 05:47:04
User entered '07 Feb 2021 00:46:59'	System	07 Feb 2021 05:47:04

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (24961d39c22dac78)', Time: '2021-02-18T15:22:07', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6d6ababa-38d6-4998-a069-cb39a183e7dc'	System	18 Feb 2021 20:22:11
User entered 'No (N)'	System	18 Feb 2021 20:22:11



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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 (24961d39c22dac78)', Time: '2021-02-18T15:22:03', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6d6ababa-38d6-4998-a069-cb39a183e7dc'	System	18 Feb 2021 20:22:11
User entered 'No (N)'	System	18 Feb 2021 20:22:11

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24961d39c22dac78)', Time: '2021-02-18T15:22:09', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '6d6ababa-38d6-4998-a069-cb39a183e7dc'	System	18 Feb 2021 20:22:11
User entered '18 Feb 2021 15:22:09'	System	18 Feb 2021 20:22:11

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (24961d39c22dac78)', Time: '2021-03-02T22:00:05-05:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '50645d81-f7e2-4934-b5a6-1e8e9aa7e2bb' User entered 'No (N)'	System	03 Mar 2021 03:00:17
	System	03 Mar 2021 03:00:17

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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 (24961d39c22dac78)', Time: '2021-03-02T22:00:07-05:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '50645d81-f7e2-4934-b5a6-1e8e9aa7e2bb' User entered 'No (N)'	System	03 Mar 2021 03:00:17

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24961d39c22dac78)', Time: '2021-03-02T22:00:09-05:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '50645d81-f7e2-4934-b5a6-1e8e9aa7e2bb'	System	03 Mar 2021 03:00:17
User entered '02 Mar 2021 22:00:09'	System	03 Mar 2021 03:00:17

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (93164ccd6836e8d3)', Time: '2021-03-18T10:42:22-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '697ce473-940c-4f29-aec9-259304b190b6'	System	18 Mar 2021 14:42:27
User entered 'No (N)'	System	18 Mar 2021 14:42:27

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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 (93164ccd6836e8d3)', Time: '2021-03-18T10:42:24-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '697ce473-940c-4f29-aec9-259304b190b6'	System	18 Mar 2021 14:42:27
User entered 'No (N)'	System	18 Mar 2021 14:42:27

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (93164ccd6836e8d3)', Time: '2021-03-18T10:42:26-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '697ce473-940c-4f29-aec9-259304b190b6' User entered '18 Mar 2021 10:42:26'	System	18 Mar 2021 14:42:27
	System	18 Mar 2021 14:42:27

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (93164ccd6836e8d3)', Time: '2021-03-25T12:09:02-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '1a613988-ac00-4baf-86b7-5352efc7f556'	System	25 Mar 2021 16:18:36
User entered 'No (N)'	System	25 Mar 2021 16:18:36



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Have you been exposed to someone with 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 (93164ccd6836e8d3)', Time: '2021-03-25T12:09:04-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '1a613988-ac00-4baf-86b7-5352efc7f556'	System	25 Mar 2021 16:18:36
User entered 'No (N)'	System	25 Mar 2021 16:18:36

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (93164ccd6836e8d3)', Time: '2021-03-25T12:09:06-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '1a613988-ac00-4baf-86b7-5352efc7f556'	System	25 Mar 2021 16:18:36
User entered '25 Mar 2021 12:09:06'	System	25 Mar 2021 16:18:36

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (93164ccd6836e8d3)', Time: '2021-03-28T00:01:29-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '2372a1f6-548c-4bb2-a6ad-6df908b56829'	System	28 Mar 2021 04:02:22
User entered 'No (N)'	System	28 Mar 2021 04:02:22

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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 (93164ccd6836e8d3)', Time: '2021-03-28T00:01:31-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '2372a1f6-548c-4bb2-a6ad-6df908b56829'	System	28 Mar 2021 04:02:22
User entered 'No (N)'	System	28 Mar 2021 04:02:22

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (93164ccd6836e8d3)', Time: '2021-03-28T00:01:33-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '2372a1f6-548c-4bb2-a6ad-6df908b56829' User entered '28 Mar 2021 00:01:33'	System	28 Mar 2021 04:02:22



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (93164ccd6836e8d3)', Time: '2021-04-04T00:20:20-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b5792596-5eff-402c-9409-d69b41ffbb43'	System	04 Apr 2021 04:20:24
User entered 'No (N)'	System	04 Apr 2021 04:20:24

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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 (93164ccd6836e8d3)', Time: '2021-04-04T00:20:21-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b5792596-5eff-402c-9409-d69b41ffbb43'	System	04 Apr 2021 04:20:24
User entered 'No (N)'	System	04 Apr 2021 04:20:24

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (93164ccd6836e8d3)', Time: '2021-04-04T00:20:23-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'b5792596-5eff-402c-9409-d69b41ffbb43'	System	04 Apr 2021 04:20:24
User entered '04 Apr 2021 00:20:23'	System	04 Apr 2021 04:20:24

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (93164ccd6836e8d3)', Time: '2021-04-11T05:38:11-05:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'ab044faa-c6cd-4694-8ad7-7f6e02421cef' User entered 'No (N)'	System	11 Apr 2021 10:38:20
	System	11 Apr 2021 10:38:20

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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 (93164ccd6836e8d3)', Time: '2021-04-11T05:38:12-05:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'ab044faa-c6cd-4694-8ad7-7f6e02421cef' User entered 'No (N)'	System	11 Apr 2021 10:38:20

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (93164ccd6836e8d3)', Time: '2021-04-11T05:38:18-05:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: 'ab044faa-c6cd-4694-8ad7-7f6e02421cef' User entered '11 Apr 2021 05:38:18'	System	11 Apr 2021 10:38:20
	System	11 Apr 2021 10:38:20

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (93164ccd6836e8d3)', Time: '2021-04-18T10:53:13-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '4f622f77-bcd6-4e77-9149-d2ca1ce9da44'	System	18 Apr 2021 14:53:26
User entered 'No (N)'	System	18 Apr 2021 14:53:26



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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 (93164ccd6836e8d3)', Time: '2021-04-18T10:53:23-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '4f622f77-bcd6-4e77-9149-d2ca1ce9da44'	System	18 Apr 2021 14:53:26
User entered 'No (N)'	System	18 Apr 2021 14:53:26

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (93164ccd6836e8d3)', Time: '2021-04-18T10:53:25-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '4f622f77-bcd6-4e77-9149-d2ca1ce9da44'	System	18 Apr 2021 14:53:26
User entered '18 Apr 2021 10:53:25'	System	18 Apr 2021 14:53:26

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (93164ccd6836e8d3)', Time: '2021-04-25T05:55:15-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '68f37eb6-529f-4158-8f9f-170f373b5223'	System	25 Apr 2021 09:55:20
User entered 'No (N)'	System	25 Apr 2021 09:55:20

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

Have you been exposed to someone with 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 (93164ccd6836e8d3)', Time: '2021-04-25T05:55:16-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '68f37eb6-529f-4158-8f9f-170f373b5223'	System	25 Apr 2021 09:55:20
User entered 'No (N)'	System	25 Apr 2021 09:55:20

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (93164ccd6836e8d3)', Time: '2021-04-25T05:55:18-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '68f37eb6-529f-4158-8f9f-170f373b5223'	System	25 Apr 2021 09:55:20
User entered '25 Apr 2021 05:55:18'	System	25 Apr 2021 09:55:20



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[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 (93164ccd6836e8d3)', Time: '2021-05-02T09:06:07-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '675d53f1-262b-4d26-8c97-e11cdfc33899'	System	02 May 2021 13:06:14
User entered 'No (N)'	System	02 May 2021 13:06:14

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Have you been exposed to someone with 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 (93164ccd6836e8d3)', Time: '2021-05-02T09:06:09-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '675d53f1-262b-4d26-8c97-e11cdfc33899'	System	02 May 2021 13:06:14
User entered 'No (N)'	System	02 May 2021 13:06:14

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (93164ccd6836e8d3)', Time: '2021-05-02T09:06:11-04:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '675d53f1-262b-4d26-8c97-e11cdfc33899'	System	02 May 2021 13:06:14
User entered '02 May 2021 09:06:11'	System	02 May 2021 13:06:14

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 09:35:45



**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 09:35:45

**US3522709**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:06:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:35:45
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 09:35:45

US3522709

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:06:13

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 15:36:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24961d39c22dac78)', Time: '2021-03-02T22:00:15-05:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '674f9c50-3a87-4fe7-8e8f-9df6ce71add7'	System	03 Mar 2021 03:00:25
User entered 'No (N)'	System	03 Mar 2021 03:00:25

**US3522709**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:36:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24961d39c22dac78)', Time: '2021-03-02T22:00:17-05:00', User OID: 'PatientReportedOutcome (US3522709)', ODM File OID: '674f9c50-3a87-4fe7-8e8f-9df6ce71add7'	System	03 Mar 2021 03:00:25
User entered '02 Mar 2021 22:00:17'	System	03 Mar 2021 03:00:25

**US3522709**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 15:25:09

US3522709

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 08:10:28
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'multiple contact attempts; see audit history ' (Site from System).	Yaman Ahmed (b) (4) (b) (4)	22 Dec 2020 21:23:08
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Dec 2020 21:22:56
User entered '22 Dec 2020' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	22 Dec 2020 21:22:56
User entered '21 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 20:06:42
User entered '18 Dec 2020'	(b) (4), (b) (6)	18 Dec 2020 15:25:09

US3522709

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: New Information	Yaman Ahmed (b) (4)	22 Dec 2020 21:22:56
User entered 'Contact Not Made (CONTACT NOT	(b) (4)	
MADE)'	(b) (4), (b) (6)	18 Dec 2020 15:25:09



US3522709

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure' reason for change: New Information	Yaman Ahmed (b) (4)	22 Dec 2020 21:22:56
User entered 'left voicemail with contact info' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 20:06:42
User entered 'Voice mail left'	(b) (4), (b) (6)	18 Dec 2020 15:25:09

**US3522709**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 15:25:15

**US3522709**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:11:46
User entered 'I'	System	18 Dec 2020 15:25:15

**US3522709**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:47:04
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	21 Jan 2021 18:45:38

**US3522709**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:47:04
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '21 Jan 2021'	(b) (4) Yaman Ahmed (b) (4)	21 Jan 2021 18:45:38

**US3522709**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:47:04
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	21 Jan 2021 18:45:38

**US3522709**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:47:04
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
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)	21 Jan 2021 18:45:38

**US3522709**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:47:04
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	21 Jan 2021 18:46:16



**US3522709**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:47:04
User entered 'I'	System	21 Jan 2021 18:46:16

**US3522709**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:47:04
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:05:19

**US3522709**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:47:04
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '18 Feb 2021'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:05:19

**US3522709**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:47:04
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:05:19

**US3522709**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:47:04
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'laparoscopic appendectomy on 10 Feb 2021. Prior to surgery, had nausea and pain for two days and went to urgent care the day before surgery (09 Feb 2021) then to ER. Has been recovering well'	Yaman Ahmed (b) (4)	18 Feb 2021 20:05:19

**US3522709**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:47:04
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:05:24

**US3522709**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:47:04
User entered 'I'	System	18 Feb 2021 20:05:24

**US3522709**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:47:04
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:35:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:53:45



**US3522709**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:47:04
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:35:23
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:53:45

**US3522709**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:47:04
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:35:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:53:45

**US3522709**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:47:04
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:35:23
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure, no hx of facial injections.'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:53:45

**US3522709**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:47:04
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:35:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:53:52

**US3522709**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:47:04
User entered 'I'	System	19 Mar 2021 13:53:52

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:56:54

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:56:54

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[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 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:56:54



**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User entered 'VISIT4'	System	07 Apr 2021 17:56:54

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:58:06

US3522709

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:58:06

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '13:50'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:58:06

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User entered '07 Apr 2021 13:50'	System	07 Apr 2021 17:58:06

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:58:06

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:58:06

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:58:06



**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '76'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:58:06

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User entered 'bpm'	System	07 Apr 2021 17:58:06

US3522709

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '14'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:58:06

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User entered 'breaths/min'	System	07 Apr 2021 17:58:06

US3522709

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '116'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:58:06

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User entered 'mmHg'	System	07 Apr 2021 17:58:06

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '71'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:58:06

US3522709

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User entered 'mmHg'	System	07 Apr 2021 17:58:06



US3522709

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:06:13**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:58:18

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:06:13**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:58:18

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:58:44

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:13**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:58:44

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '13:52'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:58:44

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User entered '07 Apr 2021 13:52'	System	07 Apr 2021 17:58:44



**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:58:53

**US3522709**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:08:19
User entered 'I'	System	07 Apr 2021 17:58:53

**US3522709**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:04

**US3522709**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:04

**US3522709**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[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 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:04

**US3522709**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 19:26:04

**US3522709**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:06:13**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:33:06

**US3522709**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:06:13**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:35:22
User entered '0'	(b) (4) Sharon Mathys (b) (4)	17 Mar 2021 19:40:05
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 09:18:34



**US3522709**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:06:13**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:33:06

**US3522709**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:06:13**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:35:22
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Sharon Mathys (b) (4)	17 Mar 2021 19:40:05
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 09:18:34

**US3522709**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:06:13**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:33:06

**US3522709**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:06:13**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:33:06

**US3522709**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:06:13**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:33:06

**US3522709**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:06:13**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:33:06

**US3522709**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:06:13**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:33:06

**US3522709**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:06:13**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'I'	System	27 Jan 2021 19:33:06



**US3522709**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'I'	System	27 Jan 2021 19:33:06

**US3522709**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:06:13**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:06:13**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered empty.	System	27 Jan 2021 20:17:06
DataPoint set to visible.	System	27 Jan 2021 19:33:06

**US3522709**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:06:13**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:06:13**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered empty.	System	27 Jan 2021 20:17:06
DataPoint set to visible.	System	27 Jan 2021 19:33:06

**US3522709**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	27 Jan 2021 20:17:06



**US3522709**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '14:34'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered '27 Jan 2021 14:34'	System	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '78'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06



**US3522709**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'bpm'	System	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '17'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'breaths/min'	System	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '118'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'mmHg'	System	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '73'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'mmHg'	System	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:06:13**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06



**US3522709**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:06:13**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:06:13**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered empty.	System	27 Jan 2021 20:17:06
DataPoint set to visible.	System	27 Jan 2021 19:33:06

**US3522709**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '15:16'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered '27 Jan 2021 15:16'	System	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '98.9' F	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06



**US3522709**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '80'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'bpm'	System	27 Jan 2021 20:17:06

US3522709

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '16'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'breaths/min'	System	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '104'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'mmHg'	System	27 Jan 2021 20:17:06



**US3522709**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '68'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'mmHg'	System	27 Jan 2021 20:17:06

**US3522709**

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

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:06:13**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:44:01

**US3522709**

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

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:06:13**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:44:01

**US3522709**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:47:18

**US3522709**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:47:18

US3522709

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

Form: Exposure

Generated On: 10 Jun 2021 08:06:13

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 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:47:18

**US3522709**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'mRNA-1273'	System	27 Jan 2021 19:47:18
DataPoint set to visible.	System	27 Jan 2021 19:33:06



**US3522709**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:47:18

**US3522709**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '14:46'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:47:18

**US3522709**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered '27 Jan 2021 14:46'	System	27 Jan 2021 19:47:18

**US3522709**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:47:18

**US3522709**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'ONCE'	System	27 Jan 2021 19:47:18

**US3522709**

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

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'INTRAMUSCULAR'	System	27 Jan 2021 19:47:18

**US3522709**

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

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:42:55

**US3522709**

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

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:13**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:42:55



**US3522709**

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

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '14:38'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:42:55

**US3522709**

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

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered '27 Jan 2021 14:38'	System	27 Jan 2021 19:42:55

**US3522709**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:06:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:43:06

**US3522709**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:43:06

**US3522709**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '14:40'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:43:06

**US3522709**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered '27 Jan 2021 14:40'	System	27 Jan 2021 19:43:06

**US3522709**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:43:22

**US3522709**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'I'	System	27 Jan 2021 19:43:22



**US3522709**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	03 Feb 2021 16:06:26

**US3522709**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '3 Feb 2021'	(b) (4) Alayna Wilder (b) (4) (b) (4)	03 Feb 2021 16:06:26

**US3522709**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alayna Wilder (b) (4)	03 Feb 2021 16:06:26

**US3522709**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
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)	03 Feb 2021 16:06:26

**US3522709**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	03 Feb 2021 16:06:32

**US3522709**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'I'	System	03 Feb 2021 16:06:32

**US3522709**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered '1'	System	03 Feb 2021 16:06:32
DataPoint set to visible.	System	03 Feb 2021 16:06:32

**US3522709**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:49:32



**US3522709**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:49:32

**US3522709**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[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 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:49:32

**US3522709**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'OLD29'	System	25 Feb 2021 14:49:32

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '14:40'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered '24 Feb 2021 14:40'	System	25 Feb 2021 14:52:17



**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '88'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'bpm'	System	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '14'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'breaths/min'	System	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '108'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17



**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'mmHg'	System	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '77'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'mmHg'	System	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	25 Feb 2021 14:52:34
Query 'Data is required. Please provide.' answered by System data change (Site from System).		25 Feb 2021 14:52:34
User entered '15:29' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 14:52:34
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Feb 2021 14:52:17
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered '24 Feb 2021 15:29'	System	25 Feb 2021 14:52:34
User entered empty.	System	25 Feb 2021 14:52:17



US3522709

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '37.0' C	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '84'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'bpm'	System	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '14'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'breaths/min'	System	25 Feb 2021 14:52:17

US3522709

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '119'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17



**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'mmHg'	System	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '78'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'mmHg'	System	25 Feb 2021 14:52:17

**US3522709**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:06:13**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:49:47

**US3522709**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:06:13**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:49:47

**US3522709**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:50:23

**US3522709**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:50:23

US3522709

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:13

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 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:50:23



**US3522709**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'mRNA-1273'	System	25 Feb 2021 14:50:23
DataPoint set to visible.	System	03 Feb 2021 16:06:32

**US3522709**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:50:23

**US3522709**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '14:59'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:50:23

**US3522709**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered '24 Feb 2021 14:59'	System	25 Feb 2021 14:50:23

US3522709

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:50:23

**US3522709**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'ONCE'	System	25 Feb 2021 14:50:23

**US3522709**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:06:13**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 14:50:23

**US3522709**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:50:37



**US3522709**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'I'	System	25 Feb 2021 14:50:37

**US3522709**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	03 Mar 2021 14:47:38

**US3522709**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '3 Mar 2021'	(b) (4) Alayna Wilder (b) (4) (b) (4)	03 Mar 2021 14:47:38

**US3522709**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	03 Mar 2021 14:47:38

**US3522709**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:06:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	(b) (4)	
	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
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.'	Alayna Wilder (b) (4)	03 Mar 2021 14:47:38
	(b) (4)	

**US3522709**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	03 Mar 2021 14:47:43

**US3522709**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:06:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:03:29
User entered 'I'	System	03 Mar 2021 14:47:43

**US3522709**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:59:14



**US3522709**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:59:14

**US3522709**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:59:14

**US3522709**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:06:13**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	07 Apr 2021 17:59:14

**US3522709**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:00:10

**US3522709**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:00:10

**US3522709**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '13:50'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:00:10

**US3522709**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
User entered '07 Apr 2021 13:50'	System	07 Apr 2021 18:00:10

**US3522709**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:00:10



**US3522709**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:00:10

**US3522709**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:00:10

**US3522709**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '76'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:00:10

**US3522709**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Apr 2021 18:00:10

**US3522709**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '14'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:00:10

**US3522709**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Apr 2021 18:00:10

**US3522709**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '116'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:00:10

**US3522709**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Apr 2021 18:00:10



**US3522709**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '71'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:00:10

**US3522709**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:06:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Apr 2021 18:00:10

**US3522709**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:06:13**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:00:22

**US3522709**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:06:13**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:00:22

**US3522709**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:00:45

**US3522709**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:13**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:00:45

**US3522709**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 12:03:51
User entered '13:52'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 18:00:45

**US3522709**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
User entered '07 Apr 2021 13:52'	System	07 Apr 2021 18:00:45



**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 08:06:13**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:11:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:05:32

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'USA-US131-2021-mRNA-1273-P301000007'	(b) (4) System	19 Feb 2021 15:37:13
User entered 'New'	(b) (4), (b) (6)	19 Feb 2021 15:37:13

US3522709

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:13

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 20:07:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 20:07:57
	(b) (4)	
Data point term sent to Coder	System	18 Feb 2021 20:07:08
User entered 'appendicitis'	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered 'No (N)'	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered 'No (N)'	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered '8 Feb 2021'	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	



**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Feb 2021 20:07:08

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered 'No (N)'	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered '11 Feb 2021' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	18 Feb 2021 20:11:46
	(b) (4)	
User entered '10 Feb 2021'	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Feb 2021 20:07:08

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08

US3522709

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	18 Feb 2021 20:10:52
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	18 Feb 2021 20:07:08
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	18 Feb 2021 20:07:08

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered '0'	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	



**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered '0'	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	

US3522709

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 09:11:14
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated' (Site from System).	Yaman Ahmed (b) (4) (b) (4)	18 Feb 2021 20:12:22
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	18 Feb 2021 20:10:52
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	18 Feb 2021 20:10:52
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	18 Feb 2021 20:10:52
User entered '1' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	18 Feb 2021 20:10:52
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	18 Feb 2021 20:10:30
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	18 Feb 2021 20:07:08

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered '10 Feb 2021' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	18 Feb 2021 20:10:30
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered '11 Feb 2021' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	18 Feb 2021 20:10:30
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	

US3522709

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Requires inpatient or prolongation of existing Hospitalization is checked, however response for ' Admitted to ICU?' is missing. Please review and reconcile' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	08 Mar 2021 11:00:15
Query 'Per CDM: Requires inpatient or prolongation of existing Hospitalization is checked, however response for ' Admitted to ICU?' is missing. Please review and reconcile' answered with 'updated to no' (Site from DM).	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 19:46:12
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	05 Mar 2021 14:23:07
User opened query 'Per CDM: Requires inpatient or prolongation of existing Hospitalization is checked, however response for ' Admitted to ICU?' is missing. Please review and reconcile' (Site from DM). User entered empty.	Sharon Mathys (b) (4) (b) (4)	05 Mar 2021 14:22:59
	(b) (4), (b) (6)	03 Mar 2021 11:26:27
	Yaman Ahmed (b) (4) (b) (4)	18 Feb 2021 20:07:08

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered '0'	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered '0'	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	



**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered '0'	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Not Related (NOT RELATED)'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Not Related (NOT RELATED)'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08

US3522709

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:13

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 27 Jan 2021, then event occurred).' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:50:59
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 27 Jan 2021, then event occurred).' answered with 'changed to none. please confirm if that is correct as understanding at site was this box was talking about the initial IP administration not the OL visit.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	01 Mar 2021 15:56:02
User entered 'None (NONE)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	01 Mar 2021 15:53:34
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 27 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:42:07
User entered 'Not Applicable (NOT APPLICABLE)'	Yaman Ahmed (b) (4) (b) (4)	18 Feb 2021 20:07:08

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered '0'	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered '1'	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered '1'	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08



**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[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 19:46:12
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08
	(b) (4)	

US3522709

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:13

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:50:54
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:50:51
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Has been sent' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	01 Mar 2021 15:58:53
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID-19 NAA test done on 2/10/2021 with negative results. Also present in discharge and lab summary' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	01 Mar 2021 15:58:47

US3522709

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:13

[Narrative](#)

Audit	User	Time (GMT)
User entered 'LAPAROSCOPIC APPENDECTOMY ON 10 FEB 202, DISCHARGED ON 11 FEB 2021. COVID-19 NAA test done on 2/10/2021 with negative results. PRIOR TO SURGERY, HAD NAUSEA AND PAIN FOR TWO DAYS AND WENT TO URGENT CARE THE DAY BEFORE SURGERY (09 FEB 2021) WHERE HE WAS GIVEN A ZOFRAN INJECTION AND LATER ON IN THE DAY HE WENT TO ER (BEAUMONT) WHERE HE RECEIVED AN IV BENADRYL (HE'S NOT SURE OF DOSES TO MEDS). POST SURGERY, HE'S BEEN RECOVERING WELL AND HAS NOT HAD TO USE IBUPROFEN GIVEN TO HIM AT DISCHARGE. HE'S RESUMED MOST OF HIS ACTIVITIES THOUGH HE'S STILL NOT ALLOWED TO BATHE AND LIFE HEAVY OBJECTS YET.' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	01 Mar 2021 15:58:19
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	26 Feb 2021 17:41:15
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	26 Feb 2021 17:41:02
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Feb 2021 20:10:30
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	18 Feb 2021 20:10:30

US3522709

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:13

[Narrative](#)

Audit	User	Time (GMT)
User entered 'laparoscopic appendectomy on 10 Feb 202, discharged on 11 Feb 2021. Prior to surgery, had nausea and pain for two days and went to urgent care the day before surgery (09 Feb 2021) where he was given a Zofran injection and later on in the day he went to ER (Beaumont) where he received an IV Benadryl (he's not sure of doses to meds). Post surgery, he's been recovering well and has not had to use Ibuprofen given to him at discharge. He's resumed most of his activities though he's still not allowed to bathe and lift heavy objects yet.' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	18 Feb 2021 20:10:30
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Feb 2021 20:07:08
User entered empty.	Yaman Ahmed (b) (4)	18 Feb 2021 20:07:08

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Feb 2021 20:07:08

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Feb 2021 20:07:08

**US3522709**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Mar 2021 14:22:59

US3522709

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 10 Jun 2021 08:06:13**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:11:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	18 Feb 2021 20:13:12



US3522709

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Feb 2021 18:13:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:13:03
Data point term sent to Coder	System	18 Feb 2021 20:14:25
User entered 'Zofran'	Yaman Ahmed (b) (4) (b) (4)	18 Feb 2021 20:14:23

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered 'No (N)'	Yaman Ahmed (b) (4)	18 Feb 2021 20:14:23
	(b) (4)	

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered 'appendicitis'	Yaman Ahmed (b) (4)	18 Feb 2021 20:14:23
	(b) (4)	

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered 'Unknown'	Yaman Ahmed (b) (4)	18 Feb 2021 20:14:23
	(b) (4)	

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered 'Other (OTHER)'	Yaman Ahmed (b) (4)	18 Feb 2021 20:14:23
	(b) (4)	

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:13**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered 'unknown'	Yaman Ahmed (b) (4)	18 Feb 2021 20:14:23
	(b) (4)	

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered 'once (ONCE)'	Yaman Ahmed (b) (4)	18 Feb 2021 20:14:23
	(b) (4)	

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	18 Feb 2021 20:14:23
	(b) (4)	



**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered 'Other (OTHER)'	Yaman Ahmed (b) (4)	18 Feb 2021 20:14:23
	(b) (4)	

US3522709

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered 'unknown'	Yaman Ahmed (b) (4)	18 Feb 2021 20:14:23
	(b) (4)	

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:13**

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered '9 Feb 2021'	Yaman Ahmed (b) (4)	18 Feb 2021 20:14:23
	(b) (4)	

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered '0'	Yaman Ahmed (b) (4)	18 Feb 2021 20:14:23
	(b) (4)	

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered 'No (N)'	Yaman Ahmed (b) (4)	18 Feb 2021 20:14:23
	(b) (4)	

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered '9 Feb 2021'	Yaman Ahmed (b) (4)	18 Feb 2021 20:14:23
	(b) (4)	

US3522709

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered 'No (N)'	Yaman Ahmed (b) (4)	18 Feb 2021 20:14:23
	(b) (4)	

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Feb 2021 20:14:23



**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Feb 2021 20:14:23

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Feb 2021 20:14:23

US3522709

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Feb 2021 22:08:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 22:08:56
Data point term sent to Coder	System	18 Feb 2021 20:16:27
User entered 'Benadryl'	Yaman Ahmed (b) (4) (b) (4)	18 Feb 2021 20:15:28

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:15:28

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'appendicitis'	Yaman Ahmed (b) (4)	18 Feb 2021 20:15:28

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'unknown'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:15:28

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Other (OTHER)'	Yaman Ahmed (b) (4)	18 Feb 2021 20:15:28

US3522709

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'unknown'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:15:28



**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'once (ONCE)'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:15:28

US3522709

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:15:28

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Intravenous (INTRAVENOUS)'	Yaman Ahmed (b) (4)	18 Feb 2021 20:15:28

US3522709

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:15:28

US3522709

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '9 Feb 2021'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:15:28

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:15:28

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:15:28

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:06:13**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '9 Feb 2021'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:15:28



**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:22
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:15:28

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:22
User entered empty.	System	18 Feb 2021 20:15:28

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:22
User entered empty.	System	18 Feb 2021 20:15:28

**US3522709**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:14:22
User entered empty.	System	18 Feb 2021 20:15:28

US3522709

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:06:13

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:11:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:12:33

**US3522709**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 08:06:13**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
	(b) (4)	
User entered '10 Feb 2021'	Yaman Ahmed (b) (4)	18 Feb 2021 20:13:01
	(b) (4)	

**US3522709**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Laparoscopic appendectomy'	(b) (4) Yaman Ahmed (b) (4) (b) (4)	18 Feb 2021 20:13:01

**US3522709**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'Adverse Event (AE)'	(b) (4) Yaman Ahmed (b) (4)	18 Feb 2021 20:13:01



**US3522709**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 08:06:13**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 19:46:12
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	18 Feb 2021 20:13:01

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'USA-US131-2021-MRNA-1273-P301000007'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'Yes (Y)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'Yes (Y)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13



**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'Paul'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'Kilgore'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered (b) (6)	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered (b) (6)	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'MI'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered (b) (6)	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:50:51
User entered 'US'	System	19 Feb 2021 15:37:43



**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	08 Mar 2021 17:48:35
User entered '2'	System	02 Mar 2021 15:51:07
User entered '1'	System	19 Feb 2021 15:37:43

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'USA-US131-2021-MRNA-1273-P301000007'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'Yes (Y)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'Yes (Y)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13



**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'Paul'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'Kilgore'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered (b) (6)	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered (b) (6)	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'MI'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered (b) (6)	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:50:51
User entered 'US'	System	19 Feb 2021 15:37:43



**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	08 Mar 2021 17:48:35
User entered '2'	System	02 Mar 2021 15:51:07
User entered '1'	System	19 Feb 2021 15:37:43

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 08:06:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '19/Feb/2021 09:37'	(b) (4) System	19 Feb 2021 15:37:43

US3522709

Folder: SAE USA-US131-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:06:13

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:50:51
User entered 'I'	(b) (4), (b) (6)	19 Feb 2021 15:37:43

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'USA-US131-2021-MRNA-1273-P301000007'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'Yes (Y)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'Yes (Y)'	System	19 Feb 2021 15:37:13



**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'Paul'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'Kilgore'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered (b) (6)	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered (b) (6)	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'MI'	System	19 Feb 2021 15:37:13



**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered (b) (6)	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:50:51
User entered 'US'	System	19 Feb 2021 15:37:43

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	08 Mar 2021 17:48:35
User entered '2'	System	02 Mar 2021 15:51:07
User entered '1'	System	19 Feb 2021 15:37:43

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 08:06:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered '02/Mar/2021 09:51'	(b) (4) System	02 Mar 2021 15:51:07

US3522709

Folder: SAE USA-US131-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:06:13

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 17:48:17
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:51:07

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'USA-US131-2021-MRNA-1273-P301000007'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'Yes (Y)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13



**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'Yes (Y)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'No (N)'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'Paul'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'Kilgore'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered (b) (6)	System	19 Feb 2021 15:37:13



**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered (b) (6)	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered 'MI'	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:37:33
User entered (b) (6)	System	19 Feb 2021 15:37:13

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 19:46:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:50:51
User entered 'US'	System	19 Feb 2021 15:37:43

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:06:13**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	08 Mar 2021 17:48:35
User entered '2'	System	02 Mar 2021 15:51:07
User entered '1'	System	19 Feb 2021 15:37:43

**US3522709**

**Folder: SAE USA-US131-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 08:06:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:42:50
User entered '08/Mar/2021 17:48'	(b) (4) System	08 Mar 2021 17:48:35

US3522709

Folder: SAE USA-US131-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:06:13

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:42:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:48:35