

US3372209 (Prod: Palm Beach Research Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:15:59

All time stamps listed in this document are displayed in GMT

US3372209

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 19:43:38

Generated On: 09 Jun 2021 17:15:59

[Participant ID](#)

US3372209

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

US3372209

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:13:14

Generated On: 09 Jun 2021 17:15:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3372209

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 23:07:09

Generated On: 09 Jun 2021 17:15:59

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	73
Age Units	YEARS
Age (Derived)	73
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	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 23:25:38

Generated On: 09 Jun 2021 17:15:59

Date of Informed Consent (<i>dd MMM yyyy</i>)	21 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 00:19:24

Generated On: 09 Jun 2021 17:15:59

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 00:51:38

Generated On: 09 Jun 2021 17:15:59

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 17 Feb 2021 00:35:27

Generated On: 09 Jun 2021 17:15:59

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 00:35:27

Generated On: 09 Jun 2021 17:15:59

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 00:35:27

Generated On: 09 Jun 2021 17:15:59

Condition	TONSILLITIS - CHRONIC
Start date (dd MMM yyyy)	UN UNK 1965
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1965
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1965
Start Year (derived)	1965
Stop Month and Year (derived)	JAN 1965
Stop Year (derived)	1965

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 00:35:27

Generated On: 09 Jun 2021 17:15:59

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1965
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1965
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1965
Start Year (derived)	1965
Stop Month and Year (derived)	JAN 1965
Stop Year (derived)	1965

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 00:35:27

Generated On: 09 Jun 2021 17:15:59

Condition	RIGHT EAR CHOLESTEATOMA
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Feb 2021 00:35:27

Generated On: 09 Jun 2021 17:15:59

Condition	RIGHT EAR MASTOIDECTOMY
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 17 Feb 2021 00:35:27

Generated On: 09 Jun 2021 17:15:59

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 03:29:38

Generated On: 09 Jun 2021 17:15:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	13:48 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 13:48
Height (xxx.x)	169.2 cm
Weight (xxx.x)	103.5 kg
BMI (xxx.x)	36.15261 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	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) 17 Feb 2021 01:07:17

Generated On: 09 Jun 2021 17:15:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 02:17:35

Generated On: 09 Jun 2021 17:15:59

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

RETIRED NETWORK ENGINEER

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 02:17:35

Generated On: 09 Jun 2021 17:15:59

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:13:15

Generated On: 09 Jun 2021 17:15:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 02:00:55

Generated On: 09 Jun 2021 17:15:59

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 187585

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) 17 Feb 2021 03:45:57

Generated On: 09 Jun 2021 17:15:59

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) 17 Feb 2021 03:45:57

Generated On: 09 Jun 2021 17:15:59

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)	21 AUG 2020
Time of assessment (00:00-23:59)	13:48 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 13:48
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	166 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 03:45:57

Generated On: 09 Jun 2021 17:15:59

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)	21 AUG 2020
Time of assessment (00:00-23:59)	15:25 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 15:25
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:07:17

Generated On: 09 Jun 2021 17:15:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 23:43:17

Generated On: 09 Jun 2021 17:15:59

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) 21 AUG 2020

What was the treatment time? (00:00-23:59) 14:51 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 14:51

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) 17 Feb 2021 00:03:01

Generated On: 09 Jun 2021 17:15:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 AUG 2020
Collection time (00:00-23:59)	14:20 (24 HR)
Collection date and time (derived)	21 AUG 2020 14:20

US3372209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:18:41

Generated On: 09 Jun 2021 17:15:59

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:18	21 AUG 2020 14:18
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:38:40

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

21 AUG 2020 15:37

PC Open Date & Time

21 AUG 2020 15:11

PC Close Date & Time

21 AUG 2020 17:41

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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 21 AUG 2020 18:42

PC Open Date & Time 21 AUG 2020 18:36

PC Close Date & Time 22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

97.2 °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

22 AUG 2020 12:13

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

23 AUG 2020 13:44

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

97.8 °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

24 AUG 2020 12:11

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 12:16

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

97.5 °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

26 AUG 2020 12:07

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

27 AUG 2020 12:08

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

21 AUG 2020 15:38

PC Open Date & Time

21 AUG 2020 15:11

PC Close Date & Time

21 AUG 2020 17:41

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

21 AUG 2020 18:43

PC Open Date & Time

21 AUG 2020 18:36

PC Close Date & Time

22 AUG 2020 11:59

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

22 AUG 2020 12:11

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

23 AUG 2020 13:45

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

24 AUG 2020 12:08

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

25 AUG 2020 12:14

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

26 AUG 2020 12:08

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

27 AUG 2020 12:08

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 15:38
PC Open Date & Time	21 AUG 2020 15:11
PC Close Date & Time	21 AUG 2020 17:41

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 18:43
PC Open Date & Time	21 AUG 2020 18:36
PC Close Date & Time	22 AUG 2020 11:59

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

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 ☒

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

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)

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 13:46
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

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 ☒

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 12:09
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

54 of 2288

EAB) (1725)

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 12:15
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

56 of 2288

EAB) (1725)

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 12:09
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 12:09
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3372209

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:34:49

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3372209

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:38:40

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372209

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:34:49

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372209

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:38:40

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372209

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:34:49

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372209

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:38:40

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372209

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:20:23

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 20:20:23

Generated On: 09 Jun 2021 17:15:59

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 SEP 2020
Time of assessment (00:00-23:59)	13:51 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 13:51
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 20:20:23

Generated On: 09 Jun 2021 17:15:59

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	15:12 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 15:12
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3372209

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:20:23

Generated On: 09 Jun 2021 17:15:59

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.

US3372209

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 20:20:23

Generated On: 09 Jun 2021 17:15:59

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 SEP 2020

What was the treatment time? (00:00-23:59) 14:39 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 14:39

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

US3372209

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:20:23

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:18:41

Generated On: 09 Jun 2021 17:15:59

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:57	23 SEP 2020 13:57
Nasopharyngeal Swab 2	No		

US3372209

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:38:40

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

98.4 °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 15:12

PC Open Date & Time 23 SEP 2020 14:59

PC Close Date & Time 23 SEP 2020 17:29

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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 98.4 °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 19:06
PC Open Date & Time	23 SEP 2020 18:24
PC Close Date & Time	24 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 12:08

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 12:48

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 13:50

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 14:45

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

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

28 SEP 2020 14:34

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

29 SEP 2020 13:18

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 15:13

PC Open Date & Time

23 SEP 2020 14:59

PC Close Date & Time

23 SEP 2020 17:29

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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 SEP 2020 19:05

PC Open Date & Time

23 SEP 2020 18:24

PC Close Date & Time

24 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

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 SEP 2020 12:06

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

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 SEP 2020 12:48

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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 SEP 2020 13:51

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

27 SEP 2020 14:43

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

28 SEP 2020 14:32

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

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 SEP 2020 13:17

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 15:14
PC Open Date & Time	23 SEP 2020 14:59
PC Close Date & Time	23 SEP 2020 17:29

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 19:05
PC Open Date & Time	23 SEP 2020 18:24
PC Close Date & Time	24 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

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 ☒

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 12:07
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 12:49
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

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 ☒

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 13:52
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

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EAB) (1725)

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 14:43
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

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)

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 14:33
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

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 ☒

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 13:17
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3372209

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:34:49

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372209

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:38:40

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372209

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:34:49

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372209

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:38:40

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372209

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:34:49

Generated On: 09 Jun 2021 17:15:59

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

If Contact Not Made, please provide Comments

US3372209

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:38:40

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372209

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:00:56

Generated On: 09 Jun 2021 17:15:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3372209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 20:00:56

Generated On: 09 Jun 2021 17:15:59

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3372209

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:00:56

Generated On: 09 Jun 2021 17:15:59

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.

US3372209

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:00:56

Generated On: 09 Jun 2021 17:15:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 OCT 2020
Collection time (00:00-23:59)	12:55 (24 HR)
Collection date and time (derived)	19 OCT 2020 12:55

US3372209

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:38:40

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 OCT 2020 16:44:58
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 OCT 2020 13:36:07
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 NOV 2020 10:52:01
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 NOV 2020 09:52:54
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

02 DEC 2020 15:52:23

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 10:17:45

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 DEC 2020 10:26:59

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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	20 DEC 2020 12:10:41
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

27 DEC 2020 07:50:24

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 12:26:55
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 08:00:04
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

17 JAN 2021 15:37:58

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 10:04:23

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

31 JAN 2021 12:35:01

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	15 FEB 2021 08:36:11
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

21 FEB 2021 11:10:22

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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	01 MAR 2021 18:57:06
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 MAR 2021 10:38:56
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

14 MAR 2021 13:06:49

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

21 MAR 2021 20:39:19

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 MAR 2021 11:19:09
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 <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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 APR 2021 17:24:34
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 11:22:13

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 11:40:19

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 13:53:54

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 JUN 2021 00:01
Patient Cloud Close Date & Time	10 JUN 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 JUL 2021 00:01
Patient Cloud Close Date & Time	08 JUL 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐
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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

Patient Cloud Open Date & Time	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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°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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐
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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 OCT 2021 00:01
Patient Cloud Close Date & Time	07 OCT 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

Date and time of submission	
Patient Cloud Open Date & Time	17 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 NOV 2021 00:01
Patient Cloud Close Date & Time	11 NOV 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 NOV 2021 00:01
Patient Cloud Close Date & Time	25 NOV 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 488

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

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

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

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

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

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐
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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 JAN 2022 00:01
Patient Cloud Close Date & Time	06 JAN 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JAN 2022 00:01
Patient Cloud Close Date & Time	27 JAN 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐ 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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 MAY 2022 00:01
Patient Cloud Close Date & Time	19 MAY 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 656

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 2022 00:01
Patient Cloud Close Date & Time	09 JUN 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2022 00:01
Patient Cloud Close Date & Time	16 JUN 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 2022 00:01
Patient Cloud Close Date & Time	30 JUN 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2022 00:01
Patient Cloud Close Date & Time	07 JUL 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐
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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2022 00:01
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐
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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐
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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2022 00:01
Patient Cloud Close Date & Time	22 SEP 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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°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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2022 00:01
Patient Cloud Close Date & Time	27 OCT 2022 23:59

US3372209

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:15:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 18:57:26

US3372209

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:34:49

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372209

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:38:40

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372209

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:34:49

Generated On: 09 Jun 2021 17:15:59

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

If Contact Not Made, please provide Comments

US3372209

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:38:40

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372209

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:34:49

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372209

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:38:40

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372209

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:34:49

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3372209

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 22:40:43

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372209

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 15:33:47

Generated On: 09 Jun 2021 17:15:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3372209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 14:29:04

Generated On: 09 Jun 2021 17:15:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	14:06 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 14:06
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (<i>xxx</i>)	55 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372209

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 15:33:47

Generated On: 09 Jun 2021 17:15:59

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.

US3372209

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 15:33:47

Generated On: 09 Jun 2021 17:15:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 MAR 2021
Collection time (00:00-23:59)	14:20 (24 HR)
Collection date and time (derived)	17 MAR 2021 14:20

US3372209

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 15:33:47

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372209

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:38:10

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372209

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:38:10

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372209

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3372209

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:15:59

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"/>

US3372209

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:15:59

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3372209

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

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:13:14

Generated On: 09 Jun 2021 17:15:59

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

Visit date (dd MMM yyyy)	19 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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US3372209

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 21:32:02

Generated On: 09 Jun 2021 17:15:59

Date of updated informed consent (<i>dd MMM yyyy</i>)	19 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>)	19 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

US3372209

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 03:45:57

Generated On: 09 Jun 2021 17:15:59

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

US3372209

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 03:45:57

Generated On: 09 Jun 2021 17:15:59

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 JAN 2021
Time of assessment (00:00-23:59)	13:45 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 13:45
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	181 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3372209

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 03:45:57

Generated On: 09 Jun 2021 17:15:59

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 JAN 2021
Time of assessment (00:00-23:59)	15:00 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 15:00
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	FPREHEAD
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	179 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3372209

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

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:07:17

Generated On: 09 Jun 2021 17:15:59

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.

US3372209

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

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 23:43:17

Generated On: 09 Jun 2021 17:15:59

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) 19 JAN 2021

What was the treatment time? (00:00-23:59) 14:28 (24 HR)

Treatment Date and Time (derived) 19 JAN 2021 14:28

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

US3372209

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 00:03:01

Generated On: 09 Jun 2021 17:15:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 JAN 2021

Collection time (00:00-23:59)

13:32 (24 HR)

Collection date and time (derived)

19 JAN 2021 13:32

US3372209

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 17:38:14

Generated On: 09 Jun 2021 17:15:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	13:29
Collection Date and Time (derived)	19 JAN 2021 13:29

US3372209

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

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:38:40

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372209

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:34:49

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372209

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:38:40

Generated On: 09 Jun 2021 17:15:59

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

US3372209

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:13:14

Generated On: 09 Jun 2021 17:15:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 03:45:57

Generated On: 09 Jun 2021 17:15:59

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 FEB 2021
Time of assessment (00:00-23:59)	12:16 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 12:16
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 03:45:57

Generated On: 09 Jun 2021 17:15:59

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 FEB 2021
Time of assessment (00:00-23:59)	13:22 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 13:22
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3372209

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:07:17

Generated On: 09 Jun 2021 17:15:59

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.

US3372209

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 23:43:17

Generated On: 09 Jun 2021 17:15:59

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

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

What was the treatment time? (00:00-23:59) 12:45 (24 HR)

Treatment Date and Time (derived) 15 FEB 2021 12:45

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

US3372209

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:38:40

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372209

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 19:22:35

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372209

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 19:22:35

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372209

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 15:33:47

Generated On: 09 Jun 2021 17:15:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3372209

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 15:33:47

Generated On: 09 Jun 2021 17:15:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	14:06 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 14:06
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (<i>xxx</i>)	55 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372209

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 15:33:47

Generated On: 09 Jun 2021 17:15:59

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.

US3372209

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 15:33:47

Generated On: 09 Jun 2021 17:15:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 MAR 2021
Collection time (00:00-23:59)	14:20 (24 HR)
Collection date and time (derived)	17 MAR 2021 14:20

US3372209

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 16:46:01

Generated On: 09 Jun 2021 17:15:59

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3372209

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Mar 2021 19:22:35

Generated On: 09 Jun 2021 17:15:59

AEID	USA-US056-2020-MRNA-1273-P30 1000011
Adverse event	ATRIAL FIBRILLATION
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)	16 DEC 2020
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)	17 DEC 2020
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 type="radio"/> Grade 4 <input checked="" 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)	16 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	17 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Mar 2021 19:22:35

Generated On: 09 Jun 2021 17:15:59

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 type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input 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	

US3372209

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Mar 2021 19:22:35

Generated On: 09 Jun 2021 17:15:59

SUBJECT WAS ADMITTED TO
THE HOSPITAL ON 16-DEC-2020
FOR DEHYDRATION AND
ATRIAL FIBRILLATION AFTER
PLAYING SEVERAL GAMES OF
TENNIS. SUBJECT HAD AN
ECHOCARDIOGRAM, CAT
HEAD, ECG COMPLETED WHILE
IN THE HOSPITAL. RESULTS
UNKNOWN, BUT PER SUBJECT
ALL TEST WERE NORMAL.

SUBJECT WAS DISCHARGED TO
HOME ON 17-DEC-2020 WITH
SYMPTOMS RESOLVED AND
WAS PLACED ON ELIQUIS 5 MG
BID.

MEDICAL RECORDS
REQUESTED.

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Mar 2021 19:22:35

Generated On: 09 Jun 2021 17:15:59

AEID	
Adverse event	DEHYDRATION
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)	16 DEC 2020
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)	17 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Form: Adverse Events (2)

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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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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	SUBJECT TOOK SODIUM CHLORIDE 0.9% FOR THIS AE
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Mar 2021 19:22:35

Generated On: 09 Jun 2021 17:15:59

AEID	
Adverse event	SYNCOPE
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)	16 DEC 2020
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)	16 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Mar 2021 19:22:35

Generated On: 09 Jun 2021 17:15:59

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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 16 Mar 2021 19:22:35

Generated On: 09 Jun 2021 17:15:59

AEID

Adverse event

PALPITATIONS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 16 Mar 2021 19:22:35

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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 type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 01:45:05

Generated On: 09 Jun 2021 17:15:59

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

Yes ☒

No ☐

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

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

Name of Medication ATENOLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 22:29:31

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Name of Medication MULTI-VITAMINS

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1995	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

Name of Medication VITAMIN C

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1995
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

Name of Medication VITAMIN B12

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1995
Start date completely unknown	False	
Ongoing?	Yes <input checked="" type="radio"/>	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

Name of Medication FISH OIL

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1995	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

Name of Medication COQ10

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1995
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

Name of Medication MAGNESIUM

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

Name of Medication MELATONIN

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN NOV 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN NOV 2019
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

Name of Medication PNEUMONIA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PNEUMONIA
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN UNK 2018
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	08 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		08 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

Name of Medication DILTIAZEM

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 DEC 2020
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☐
No ☒

Indication DEHYDRATION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 19 Feb 2021 22:29:31

Generated On: 09 Jun 2021 17:15:59

	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)		16 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 DEC 2020
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"/>

US3372209

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 18:08:51

Generated On: 09 Jun 2021 17:15:59

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Feb 2021 18:08:51

Generated On: 09 Jun 2021 17:15:59

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
16 DEC 2020	CAT SCAN BRAIN	Adverse Event	
16 DEC 2020	CHEST X-RAY	Adverse Event	
16 DEC 2020	ELECTROCARDIOGRAM	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:15:59

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 17 Feb 2021 02:51:11

Generated On: 09 Jun 2021 17:15:59

SAEID	USA-US056-2020-MRNA-1273-P301000011
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	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

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Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 17 Feb 2021 02:51:11

Generated On: 09 Jun 2021 17:15:59

SAEID	USA-US056-2020-MRNA-1273-P301000011
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	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	21/DEC/2020 13:36
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

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 17 Feb 2021 02:51:11

Generated On: 09 Jun 2021 17:15:59

SAEID	USA-US056-2020-MRNA-1273-P301000011
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	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	25/JAN/2021 14:49
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

US3372209 (Prod: Palm Beach Research Center)

US3372209

Form: Participant Creation

Generated On: 09 Jun 2021 17:15:59

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:43:38
User entered 'US3372209'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 17:09:49

US3372209

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:13:15
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:23

US3372209

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:13:15
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 17:09:50

US3372209

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[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 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:13:15
User entered 'Clinic (Clinic)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:23

US3372209

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'SCRN'	System	21 Aug 2020 18:26:23

US3372209

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:07:09
User entered (b) (6) 1947'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 17:09:51

US3372209

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:07:09
User entered '73'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:37

US3372209

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'YEARS'	System	21 Aug 2020 18:26:37

US3372209

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered '73'	System	21 Aug 2020 18:26:51

US3372209

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:07:09
User entered 'Male (M)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:37

US3372209

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:07:09
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:37

US3372209

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:07:09
User entered 'I'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:37

US3372209

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:07:09
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:37

US3372209

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:07:09
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:37

US3372209

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:07:09
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:37

US3372209

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:07:09
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:37

US3372209

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:07:09
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:37

US3372209

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:07:09
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:37

US3372209

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:07:09
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:37

US3372209

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:07:09
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:37

US3372209

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:25:38
User entered '21 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:51

US3372209

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'Aug 2020'	System	21 Aug 2020 18:26:51

US3372209

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered '2020'	System	21 Aug 2020 18:26:51

US3372209

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:25:38
User entered 'Amendment 2 (2)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:51

US3372209

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:25:38
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:51

US3372209

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:25:38
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:51

US3372209

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:25:38
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:51

US3372209

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:25:38
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:51

US3372209

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:25:38
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 17:09:50

US3372209

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'I'	System	21 Aug 2020 18:26:57

US3372209

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:19:24
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:26:57

US3372209

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:15:59

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:51:38
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 15:20:44

US3372209

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:23:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:23:43
Data point term sent to Coder	System	23 Oct 2020 15:22:37
User entered 'hypertension'	Peter Jacob (b) (4)	23 Oct 2020 15:22:01

US3372209

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'un UNK 2000'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:22:01

US3372209

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:22:01

US3372209

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:22:01

US3372209

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:22:01

US3372209

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:22:01

US3372209

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'Jan 2000'	System	23 Oct 2020 15:22:01

US3372209

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered '2000'	System	23 Oct 2020 15:22:01

US3372209

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered empty.	System	23 Oct 2020 15:22:01

US3372209

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered empty.	System	23 Oct 2020 15:22:01

US3372209

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:23:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:23:43
Data point term sent to Coder	System	23 Oct 2020 15:22:39
User entered 'hypercholesterolemia'	Peter Jacob (b) (4)	23 Oct 2020 15:22:17

US3372209

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'un UNK 2005'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:22:17

US3372209

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:22:17

US3372209

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:22:17

US3372209

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:22:17

US3372209

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:22:17

US3372209

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'Jan 2005'	System	23 Oct 2020 15:22:17

US3372209

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered '2005'	System	23 Oct 2020 15:22:17

US3372209

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered empty.	System	23 Oct 2020 15:22:17

US3372209

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered empty.	System	23 Oct 2020 15:22:17

US3372209

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:15:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Chronic tonsillitis, LLT: Chronic tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:24:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:24:30
Data point term sent to Coder	System	23 Oct 2020 15:23:40
User entered 'tonsillitis - chronic'	Peter Jacob (b) (4)	23 Oct 2020 15:23:29

US3372209

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'un UNK 1965'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:23:29

US3372209

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:23:29

US3372209

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:15:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 15:23:29

US3372209

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'un UNK 1965'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:23:29

US3372209

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:15:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:23:29

US3372209

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'Jan 1965'	System	23 Oct 2020 15:23:29

US3372209

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered '1965'	System	23 Oct 2020 15:23:29

US3372209

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'Jan 1965'	System	23 Oct 2020 15:23:29

US3372209

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered '1965'	System	23 Oct 2020 15:23:29

US3372209

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:15:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:31:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:31:38
Data point term sent to Coder	System	23 Oct 2020 15:30:56
User entered 'tonsillectomy'	Peter Jacob (b) (4)	23 Oct 2020 15:30:42

US3372209

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'un UNK 1965'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:30:42

US3372209

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:30:42

US3372209

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:15:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:30:42

US3372209

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'un UNK 1965'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:30:42

US3372209

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:15:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:30:42

US3372209

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'Jan 1965'	System	23 Oct 2020 15:30:42

US3372209

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered '1965'	System	23 Oct 2020 15:30:42

US3372209

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'Jan 1965'	System	23 Oct 2020 15:30:42

US3372209

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered '1965'	System	23 Oct 2020 15:30:42

US3372209

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:15:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Miscellaneous and site unspecified neoplasms benign, HLT: Aural neoplasms benign, PT: Cholesteatoma, LLT: Cholesteatoma - version MedDRA\\23.0.	Coder Import (b) (4)	24 Oct 2020 05:57:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Oct 2020 05:57:23
Data point term sent to Coder	System	23 Oct 2020 15:36:08
User entered 'right ear cholesteatoma'	Peter Jacob (b) (4)	23 Oct 2020 15:36:01

US3372209

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'un UNK 2004'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:36:01

US3372209

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:36:01

US3372209

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:15:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:36:01

US3372209

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'un UNK 2004'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:36:01

US3372209

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:15:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:36:01

US3372209

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'Jan 2004'	System	23 Oct 2020 15:36:01

US3372209

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered '2004'	System	23 Oct 2020 15:36:01

US3372209

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'Jan 2004'	System	23 Oct 2020 15:36:01

US3372209

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered '2004'	System	23 Oct 2020 15:36:01

US3372209

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:15:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Mastoid therapeutic procedures, PT: Mastoidectomy, LLT: Mastoidectomy - version MedDRA\\23.0.	Coder Import (b) (4)	24 Oct 2020 05:57:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Oct 2020 05:57:23
Data point term sent to Coder	System	23 Oct 2020 15:38:10
User entered 'right ear mastoidectomy'	Peter Jacob (b) (4)	23 Oct 2020 15:37:32

US3372209

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'un UNK 2004'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:37:32

US3372209

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:37:32

US3372209

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:15:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:37:32

US3372209

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'un UNK 2004'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:37:32

US3372209

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:15:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:37:32

US3372209

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'Jan 2004'	System	23 Oct 2020 15:37:32

US3372209

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered '2004'	System	23 Oct 2020 15:37:32

US3372209

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'Jan 2004'	System	23 Oct 2020 15:37:32

US3372209

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered '2004'	System	23 Oct 2020 15:37:32

US3372209

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:15:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:48:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:48:29
Data point term sent to Coder	System	23 Oct 2020 15:47:33
User entered 'prostate cancer'	Peter Jacob (b) (4)	23 Oct 2020 15:46:48

US3372209

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:46:48

US3372209

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:46:48

US3372209

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:15:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:46:48

US3372209

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:46:48

US3372209

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:15:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:35:27
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:46:48

US3372209

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'Jan 2018'	System	23 Oct 2020 15:46:48

US3372209

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered '2018'	System	23 Oct 2020 15:46:48

US3372209

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'Jan 2018'	System	23 Oct 2020 15:46:48

US3372209

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered '2018'	System	23 Oct 2020 15:46:48

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:29:38
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Aug 2020 17:53:18

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:29:38
User entered '21 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Aug 2020 17:53:18

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:29:38
User entered '13:48'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Aug 2020 17:53:18

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered '21 Aug 2020 13:48'	System	28 Aug 2020 17:53:18

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:29:38
User entered '169.2' cm	(b) (4) Peter Jacob (b) (4)	28 Aug 2020 17:53:18
DataPoint set to visible.	(b) (4) System	21 Aug 2020 18:26:57

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:29:38
User entered '103.5' kg	(b) (4) Peter Jacob (b) (4)	28 Aug 2020 17:53:18
DataPoint set to visible.	(b) (4) System	21 Aug 2020 18:26:57

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered '36.15261'	System	28 Aug 2020 17:53:18
DataPoint set to visible.	System	21 Aug 2020 18:26:57

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'kg/m2'	System	28 Aug 2020 17:53:18
DataPoint set to visible.	System	21 Aug 2020 18:26:57

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:29:38
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:31:22
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 17:30:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 17:30:21
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:49:29
User entered '36.7' C	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 17:53:18

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:29:38
User entered empty; reason for change Data Entry Error	(b) (4)	
	Peter Jacob (b) (4)	29 Sep 2020 17:30:21
User entered 'Oral (Oral)'	(b) (4)	
	Peter Jacob (b) (4)	28 Aug 2020 17:53:18
	(b) (4)	

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:29:38
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Aug 2020 17:53:18

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:29:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 17:30:21
User entered '58'	Peter Jacob (b) (4)	28 Aug 2020 17:53:18
	(b) (4)	

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'bpm'	System	28 Aug 2020 17:53:18

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:29:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 17:30:21
User entered '20'	Peter Jacob (b) (4)	28 Aug 2020 17:53:18
	(b) (4)	

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'breaths/min'	System	28 Aug 2020 17:53:18

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:29:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 17:30:21
User entered '166'	Peter Jacob (b) (4)	28 Aug 2020 17:53:18
	(b) (4)	

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'mmHg'	System	28 Aug 2020 17:53:18

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:29:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 17:30:21
User entered '88'	Peter Jacob (b) (4)	28 Aug 2020 17:53:18
	(b) (4)	

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User entered 'mmHg'	System	28 Aug 2020 17:53:18

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29

US3372209

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29

US3372209

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:07:18
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	28 Aug 2020 17:56:33

US3372209

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:07:18
User entered '21 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Aug 2020 17:56:33

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered 'Retired Network Engineer'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered 'I'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:01:29
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:17:35
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:43

US3372209

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:13:15
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:56

US3372209

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:13:15
User entered '21 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:56

US3372209

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:13:15
User entered 'Clinic (Clinic)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:27:56

US3372209

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered 'VISIT1'	System	21 Aug 2020 18:27:56

US3372209

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:00:55
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 18:29:27

US3372209

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:00:55
User entered '187585'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 18:29:27

US3372209

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:00:55
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 18:29:27

US3372209

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:00:55
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:37:36

US3372209

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:00:55
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:37:36

US3372209

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:00:55
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:37:36

US3372209

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:00:55
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:37:36

US3372209

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:15:59

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:00:55
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 18:37:36

US3372209

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:15:59

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:00:55
User closed query 'Per CDM: This field requires yes or no. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:41:53
Query 'Per CDM: This field requires yes or no. Please complete.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	06 Nov 2020 21:02:46
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	06 Nov 2020 21:02:32
User opened query 'Per CDM: This field requires yes or no. Please complete.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:04:08
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:38:24
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:04:24

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:31:18
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:18:34
answered with 'data updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:18:23
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:49:37
User entered '169.2' cm	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:18:23
User entered '103.5' kg	Peter Jacob (b) (4)	28 Aug 2020 18:01:02
	(b) (4)	

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:31:18
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:18:34
answered with 'data updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:18:23
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:49:37
User entered '169.2' cm	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:18:23
User entered '103.5' kg	Peter Jacob (b) (4)	28 Aug 2020 18:01:02
	(b) (4)	

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '21 Aug 2020'	(b) (4) Peter Jacob (b) (4)	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '13:48'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered '21 Aug 2020 13:48'	System	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '36.7' C	(b) (4) Peter Jacob (b) (4)	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4)	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered empty.	(b) (4) Peter Jacob (b) (4)	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '58'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered 'bpm'	System	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '20'	(b) (4) Peter Jacob (b) (4)	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered 'breaths/min'	System	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 18:07:02
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 18:01:12
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Aug 2020 18:01:02
User entered '166'	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered 'mmHg'	System	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '88'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered 'mmHg'	System	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:31:18
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:18:34
answered with 'data updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:18:23
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:49:37
User entered '169.2' cm	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 18:01:02

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:18:23
User entered '103.5' kg	Peter Jacob (b) (4)	28 Aug 2020 18:01:02
	(b) (4)	

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	28 Aug 2020 18:02:21

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	28 Aug 2020 18:02:21

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '21 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Aug 2020 18:02:21

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '15:25'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Aug 2020 18:02:21

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered '21 Aug 2020 15:25'	System	28 Aug 2020 18:02:21

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '36.4' C	(b) (4) Peter Jacob (b) (4)	28 Aug 2020 18:02:21

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Aug 2020 18:02:21

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered empty.	(b) (4) Peter Jacob (b) (4)	28 Aug 2020 18:02:21

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '56'	(b) (4) Peter Jacob (b) (4)	28 Aug 2020 18:02:21

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered 'bpm'	System	28 Aug 2020 18:02:21

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '18'	(b) (4) Peter Jacob (b) (4)	28 Aug 2020 18:02:21

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered 'breaths/min'	System	28 Aug 2020 18:02:21

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '154'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Aug 2020 18:02:21

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered 'mmHg'	System	28 Aug 2020 18:02:21

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '72'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Aug 2020 18:02:21

US3372209

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered 'mmHg'	System	28 Aug 2020 18:02:21

US3372209

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:07:18
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	28 Aug 2020 18:02:27

US3372209

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:07:18
User entered '21 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	28 Aug 2020 18:02:27

US3372209

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:43:17
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 19:01:55

US3372209

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:43:17
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 19:01:55

US3372209

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:43:17
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 19:01:55

US3372209

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 19:01:55

US3372209

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:43:17
User entered '21 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 19:01:55

US3372209

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:43:17
User entered '14:51'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 19:01:55

US3372209

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered '21 Aug 2020 14:51'	System	21 Aug 2020 19:01:55

US3372209

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:43:17
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 19:01:55

US3372209

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered 'ONCE'	System	21 Aug 2020 19:01:55

US3372209

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 19:01:55

US3372209

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:03:01
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 19:02:16

US3372209

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:03:01
User entered '21 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 19:02:16

US3372209

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:03:01
User entered '14:20'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 19:02:16

US3372209

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered '21 Aug 2020 14:20'	System	21 Aug 2020 19:02:16

US3372209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:15:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:18:41
User entered '21 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 19:02:31

US3372209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:15:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kimarie Lee-Russell (b) (4)	21 Aug 2020 19:02:31

US3372209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:18:41
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 19:02:31

US3372209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:15:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:18:41
User entered '14:18'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 19:02:31

US3372209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered '21 Aug 2020 14:18'	System	21 Aug 2020 19:02:31

US3372209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kimarie Lee-Russell (b) (4)	21 Aug 2020 19:02:31

US3372209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:18:41
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 19:02:31

US3372209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:18:41
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	21 Aug 2020 19:02:31

US3372209

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered empty.	System	21 Aug 2020 19:02:31

US3372209

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:38:40
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	28 Aug 2020 18:02:31

US3372209

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered 'I'	System	28 Aug 2020 18:02:31

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T15:37:02', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b9c1a1fc-65ce-45c1-a1c2-3c71968f71ac'	System	21 Aug 2020 19:37:40
User entered 'Yes (Y)'	System	21 Aug 2020 19:37:40

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T15:37:18', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b9c1a1fc-65ce-45c1-a1c2-3c71968f71ac'	System	21 Aug 2020 19:37:40
User entered '97.6'	System	21 Aug 2020 19:37:40

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T15:37:26', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b9c1a1fc-65ce-45c1-a1c2-3c71968f71ac'	System	21 Aug 2020 19:37:40
User entered 'No (N)'	System	21 Aug 2020 19:37:40

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T15:37:38', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b9c1a1fc-65ce-45c1-a1c2-3c71968f71ac'	System	21 Aug 2020 19:37:40
User entered '21 Aug 2020 15:37'	System	21 Aug 2020 19:37:40

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '21 Aug 2020 15:11'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '21 Aug 2020 17:41'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T18:41:31', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '0e4296c2-2d0d-459e-bd1f-f8b8f12f5821'	System	21 Aug 2020 22:42:13
User entered 'Yes (Y)'	System	21 Aug 2020 22:42:13

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T18:41:55', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '0e4296c2-2d0d-459e-bd1f-f8b8f12f5821'	System	21 Aug 2020 22:42:13
User entered '97.3'	System	21 Aug 2020 22:42:13

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T18:42:02', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '0e4296c2-2d0d-459e-bd1f-f8b8f12f5821'	System	21 Aug 2020 22:42:13
User entered 'No (N)'	System	21 Aug 2020 22:42:13

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T18:42:11', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '0e4296c2-2d0d-459e-bd1f-f8b8f12f5821'	System	21 Aug 2020 22:42:13
User entered '21 Aug 2020 18:42'	System	21 Aug 2020 22:42:13

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '21 Aug 2020 18:36'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 2'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-22T12:12:40', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b35021b7-d7e0-496c-a12a-c108ede05423'	System	22 Aug 2020 16:13:16
User entered 'Yes (Y)'	System	22 Aug 2020 16:13:16

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-22T12:12:56', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b35021b7-d7e0-496c-a12a-c108ede05423'	System	22 Aug 2020 16:13:16
User entered '97.2'	System	22 Aug 2020 16:13:16

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-22T12:13:02', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b35021b7-d7e0-496c-a12a-c108ede05423'	System	22 Aug 2020 16:13:16
User entered 'No (N)'	System	22 Aug 2020 16:13:16

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-22T12:13:13', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b35021b7-d7e0-496c-a12a-c108ede05423'	System	22 Aug 2020 16:13:16
User entered '22 Aug 2020 12:13'	System	22 Aug 2020 16:13:16

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 3'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-23T13:44:18', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b7e9935e-c9e4-4c63-90cc-d61a36fa8189'	System	23 Aug 2020 17:44:44
User entered 'Yes (Y)'	System	23 Aug 2020 17:44:44

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-23T13:44:27', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b7e9935e-c9e4-4c63-90cc-d61a36fa8189'	System	23 Aug 2020 17:44:44
User entered '97.9'	System	23 Aug 2020 17:44:44

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-23T13:44:36', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b7e9935e-c9e4-4c63-90cc-d61a36fa8189'	System	23 Aug 2020 17:44:44
User entered 'No (N)'	System	23 Aug 2020 17:44:44

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-23T13:44:42', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b7e9935e-c9e4-4c63-90cc-d61a36fa8189'	System	23 Aug 2020 17:44:44
User entered '23 Aug 2020 13:44'	System	23 Aug 2020 17:44:44

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 4'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-24T12:10:02', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '772f7a20-eaeb-4183-b64f-0636c49a6692'	System	24 Aug 2020 16:11:08
User entered 'Yes (Y)'	System	24 Aug 2020 16:11:08

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-24T12:10:53', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '772f7a20-eaeb-4183-b64f-0636c49a6692'	System	24 Aug 2020 16:11:08
User entered '97.8'	System	24 Aug 2020 16:11:08

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-24T12:10:57', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '772f7a20-eaeb-4183-b64f-0636c49a6692'	System	24 Aug 2020 16:11:08
User entered 'No (N)'	System	24 Aug 2020 16:11:08

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-24T12:11:01', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '772f7a20-eaeb-4183-b64f-0636c49a6692'	System	24 Aug 2020 16:11:08
User entered '24 Aug 2020 12:11'	System	24 Aug 2020 16:11:08

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 5'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-25T12:15:31', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'e2548a77-c771-414a-83f0-65fac3e71ca4'	System	25 Aug 2020 16:16:04
User entered 'Yes (Y)'	System	25 Aug 2020 16:16:04

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-25T12:15:54', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'e2548a77-c771-414a-83f0-65fac3e71ca4'	System	25 Aug 2020 16:16:04
User entered '98.0'	System	25 Aug 2020 16:16:04

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-25T12:15:58', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'e2548a77-c771-414a-83f0-65fac3e71ca4'	System	25 Aug 2020 16:16:04
User entered 'No (N)'	System	25 Aug 2020 16:16:04

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-25T12:16:02', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'e2548a77-c771-414a-83f0-65fac3e71ca4'	System	25 Aug 2020 16:16:04
User entered '25 Aug 2020 12:16'	System	25 Aug 2020 16:16:04

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 6'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-26T12:07:33', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '8a5e3b5a-12d2-4da1-8b09-08245080ef84'	System	26 Aug 2020 16:07:55
User entered 'Yes (Y)'	System	26 Aug 2020 16:07:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-26T12:07:42', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '8a5e3b5a-12d2-4da1-8b09-08245080ef84'	System	26 Aug 2020 16:07:55
User entered '97.5'	System	26 Aug 2020 16:07:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-26T12:07:47', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '8a5e3b5a-12d2-4da1-8b09-08245080ef84'	System	26 Aug 2020 16:07:55
User entered 'No (N)'	System	26 Aug 2020 16:07:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-26T12:07:52', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '8a5e3b5a-12d2-4da1-8b09-08245080ef84'	System	26 Aug 2020 16:07:55
User entered '26 Aug 2020 12:07'	System	26 Aug 2020 16:07:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 7'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-27T12:08:01', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '494fac30-6ae4-4ec8-8566-ebf2db4efd9b'	System	27 Aug 2020 16:08:47
User entered 'Yes (Y)'	System	27 Aug 2020 16:08:47

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-27T12:08:11', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '494fac30-6ae4-4ec8-8566-ebf2db4efd9b'	System	27 Aug 2020 16:08:47
User entered '97.4'	System	27 Aug 2020 16:08:47

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-27T12:08:16', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '494fac30-6ae4-4ec8-8566-ebf2db4efd9b'	System	27 Aug 2020 16:08:47
User entered 'No (N)'	System	27 Aug 2020 16:08:47

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-27T12:08:21', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '494fac30-6ae4-4ec8-8566-ebf2db4efd9b'	System	27 Aug 2020 16:08:47
User entered '27 Aug 2020 12:08'	System	27 Aug 2020 16:08:47

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T15:37:50', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '1f65fdc8-6680-4f49-92d3-a496360e3e69'	System	21 Aug 2020 19:38:13
User entered 'None (1)'	System	21 Aug 2020 19:38:13

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T15:37:55', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '1f65fdc8-6680-4f49-92d3-a496360e3e69'	System	21 Aug 2020 19:38:13
User entered 'No (N)'	System	21 Aug 2020 19:38:13

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T15:37:58', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '1f65fdc8-6680-4f49-92d3-a496360e3e69'	System	21 Aug 2020 19:38:13
User entered 'No (N)'	System	21 Aug 2020 19:38:13

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T15:38:05', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '1f65fdc8-6680-4f49-92d3-a496360e3e69'	System	21 Aug 2020 19:38:13
User entered 'None (1)'	System	21 Aug 2020 19:38:13

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T15:38:11', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '1f65fdc8-6680-4f49-92d3-a496360e3e69'	System	21 Aug 2020 19:38:13
User entered '21 Aug 2020 15:38'	System	21 Aug 2020 19:38:13

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '21 Aug 2020 15:11'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '21 Aug 2020 17:41'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T18:42:21', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '1ff881b9-36e6-43c2-a113-b0da0b9a8d48'	System	21 Aug 2020 22:43:03
User entered 'None (1)'	System	21 Aug 2020 22:43:03

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T18:42:27', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '1ff881b9-36e6-43c2-a113-b0da0b9a8d48'	System	21 Aug 2020 22:43:03
User entered 'No (N)'	System	21 Aug 2020 22:43:03

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T18:42:33', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '1ff881b9-36e6-43c2-a113-b0da0b9a8d48'	System	21 Aug 2020 22:43:03
User entered 'No (N)'	System	21 Aug 2020 22:43:03

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T18:42:46', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '1ff881b9-36e6-43c2-a113-b0da0b9a8d48'	System	21 Aug 2020 22:43:03
User entered 'None (1)'	System	21 Aug 2020 22:43:03

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T18:43:00', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '1ff881b9-36e6-43c2-a113-b0da0b9a8d48'	System	21 Aug 2020 22:43:03
User entered '21 Aug 2020 18:43'	System	21 Aug 2020 22:43:03

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '21 Aug 2020 18:36'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 2'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-22T12:11:17', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '77287cf7-bcb8-4d2d-825e-ba380b202eb3'	System	22 Aug 2020 16:11:40
User entered 'None (1)'	System	22 Aug 2020 16:11:40

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-22T12:11:21', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '77287cf7-bcb8-4d2d-825e-ba380b202eb3'	System	22 Aug 2020 16:11:40
User entered 'No (N)'	System	22 Aug 2020 16:11:40

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-22T12:11:24', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '77287cf7-bcb8-4d2d-825e-ba380b202eb3'	System	22 Aug 2020 16:11:40
User entered 'No (N)'	System	22 Aug 2020 16:11:40

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-22T12:11:32', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '77287cf7-bcb8-4d2d-825e-ba380b202eb3'	System	22 Aug 2020 16:11:40
User entered 'None (1)'	System	22 Aug 2020 16:11:40

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-22T12:11:36', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '77287cf7-bcb8-4d2d-825e-ba380b202eb3'	System	22 Aug 2020 16:11:40
User entered '22 Aug 2020 12:11'	System	22 Aug 2020 16:11:40

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 3'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-23T13:44:50', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '5e0dc558-702d-47b6-b0a9-5048f53c3ea7'	System	23 Aug 2020 17:45:20
User entered 'None (1)'	System	23 Aug 2020 17:45:20

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-23T13:44:54', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '5e0dc558-702d-47b6-b0a9-5048f53c3ea7'	System	23 Aug 2020 17:45:20
User entered 'No (N)'	System	23 Aug 2020 17:45:20

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-23T13:44:59', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '5e0dc558-702d-47b6-b0a9-5048f53c3ea7'	System	23 Aug 2020 17:45:20
User entered 'No (N)'	System	23 Aug 2020 17:45:20

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-23T13:45:07', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '5e0dc558-702d-47b6-b0a9-5048f53c3ea7'	System	23 Aug 2020 17:45:20
User entered 'None (1)'	System	23 Aug 2020 17:45:20

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-23T13:45:14', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '5e0dc558-702d-47b6-b0a9-5048f53c3ea7'	System	23 Aug 2020 17:45:20
User entered '23 Aug 2020 13:45'	System	23 Aug 2020 17:45:20

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 4'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-24T12:07:52', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'cac52cdd-94f8-43ba-90bd-1aa5e73133e8'	System	24 Aug 2020 16:08:22
User entered 'None (1)'	System	24 Aug 2020 16:08:22

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-24T12:07:56', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'cac52cdd-94f8-43ba-90bd-1aa5e73133e8'	System	24 Aug 2020 16:08:22
User entered 'No (N)'	System	24 Aug 2020 16:08:22

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-24T12:08:00', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'cac52cdd-94f8-43ba-90bd-1aa5e73133e8'	System	24 Aug 2020 16:08:22
User entered 'No (N)'	System	24 Aug 2020 16:08:22

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-24T12:08:08', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'cac52cdd-94f8-43ba-90bd-1aa5e73133e8'	System	24 Aug 2020 16:08:22
User entered 'None (1)'	System	24 Aug 2020 16:08:22

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-24T12:08:18', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'cac52cdd-94f8-43ba-90bd-1aa5e73133e8'	System	24 Aug 2020 16:08:22
User entered '24 Aug 2020 12:08'	System	24 Aug 2020 16:08:22

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 5'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-25T12:14:26', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'e3c72565-fedf-4f65-8206-7547b0a515fc'	System	25 Aug 2020 16:14:48
User entered 'None (1)'	System	25 Aug 2020 16:14:48

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-25T12:14:29', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'e3c72565-fedf-4f65-8206-7547b0a515fc'	System	25 Aug 2020 16:14:48
User entered 'No (N)'	System	25 Aug 2020 16:14:48

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-25T12:14:32', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'e3c72565-fedf-4f65-8206-7547b0a515fc'	System	25 Aug 2020 16:14:48
User entered 'No (N)'	System	25 Aug 2020 16:14:48

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-25T12:14:40', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'e3c72565-fedf-4f65-8206-7547b0a515fc'	System	25 Aug 2020 16:14:48
User entered 'None (1)'	System	25 Aug 2020 16:14:48

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-25T12:14:44', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'e3c72565-fedf-4f65-8206-7547b0a515fc'	System	25 Aug 2020 16:14:48
User entered '25 Aug 2020 12:14'	System	25 Aug 2020 16:14:48

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 6'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-26T12:08:02', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'a136a3af-b120-4516-817d-de2f0262b4d8'	System	26 Aug 2020 16:08:39
User entered 'None (1)'	System	26 Aug 2020 16:08:39

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-26T12:08:06', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'a136a3af-b120-4516-817d-de2f0262b4d8'	System	26 Aug 2020 16:08:39
User entered 'No (N)'	System	26 Aug 2020 16:08:39

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-26T12:08:10', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'a136a3af-b120-4516-817d-de2f0262b4d8'	System	26 Aug 2020 16:08:39
User entered 'No (N)'	System	26 Aug 2020 16:08:39

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-26T12:08:31', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'a136a3af-b120-4516-817d-de2f0262b4d8'	System	26 Aug 2020 16:08:39
User entered 'None (1)'	System	26 Aug 2020 16:08:39

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-26T12:08:35', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'a136a3af-b120-4516-817d-de2f0262b4d8'	System	26 Aug 2020 16:08:39
User entered '26 Aug 2020 12:08'	System	26 Aug 2020 16:08:39

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 7'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-27T12:08:30', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '9f4ef720-013f-40c5-9d9e-5cbc7d3d13aa'	System	27 Aug 2020 16:08:58
User entered 'None (1)'	System	27 Aug 2020 16:08:58

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-27T12:08:34', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '9f4ef720-013f-40c5-9d9e-5cbc7d3d13aa'	System	27 Aug 2020 16:08:58
User entered 'No (N)'	System	27 Aug 2020 16:08:58

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-27T12:08:39', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '9f4ef720-013f-40c5-9d9e-5cbc7d3d13aa'	System	27 Aug 2020 16:08:58
User entered 'No (N)'	System	27 Aug 2020 16:08:58

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-27T12:08:51', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '9f4ef720-013f-40c5-9d9e-5cbc7d3d13aa'	System	27 Aug 2020 16:08:58
User entered 'None (1)'	System	27 Aug 2020 16:08:58

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-27T12:08:55', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '9f4ef720-013f-40c5-9d9e-5cbc7d3d13aa'	System	27 Aug 2020 16:08:58
User entered '27 Aug 2020 12:08'	System	27 Aug 2020 16:08:58

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T15:38:23', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b9aca8c8-a482-4ba1-80c1-3a7a45706b6e'	System	21 Aug 2020 19:38:57
User entered 'None (0)'	System	21 Aug 2020 19:38:57

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T15:38:26', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b9aca8c8-a482-4ba1-80c1-3a7a45706b6e'	System	21 Aug 2020 19:38:57
User entered 'None (0)'	System	21 Aug 2020 19:38:57

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T15:38:30', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b9aca8c8-a482-4ba1-80c1-3a7a45706b6e'	System	21 Aug 2020 19:38:57
User entered 'None (0)'	System	21 Aug 2020 19:38:57

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T15:38:33', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b9aca8c8-a482-4ba1-80c1-3a7a45706b6e'	System	21 Aug 2020 19:38:57
User entered 'None (0)'	System	21 Aug 2020 19:38:57

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T15:38:36', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b9aca8c8-a482-4ba1-80c1-3a7a45706b6e'	System	21 Aug 2020 19:38:57
User entered 'None (0)'	System	21 Aug 2020 19:38:57

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T15:38:39', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b9aca8c8-a482-4ba1-80c1-3a7a45706b6e'	System	21 Aug 2020 19:38:57
User entered 'None (0)'	System	21 Aug 2020 19:38:57

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T15:38:49', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b9aca8c8-a482-4ba1-80c1-3a7a45706b6e'	System	21 Aug 2020 19:38:57
User entered 'No (N)'	System	21 Aug 2020 19:38:57

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T15:38:54', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b9aca8c8-a482-4ba1-80c1-3a7a45706b6e'	System	21 Aug 2020 19:38:57
User entered '21 Aug 2020 15:38'	System	21 Aug 2020 19:38:57

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '21 Aug 2020 15:11'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '21 Aug 2020 17:41'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T18:43:13', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f3d9d496-678f-4ae8-be88-dbc0bd066771'	System	21 Aug 2020 22:43:47
User entered 'None (0)'	System	21 Aug 2020 22:43:47

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T18:43:21', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f3d9d496-678f-4ae8-be88-dbc0bd066771'	System	21 Aug 2020 22:43:47
User entered 'None (0)'	System	21 Aug 2020 22:43:47

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T18:43:24', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f3d9d496-678f-4ae8-be88-dbc0bd066771'	System	21 Aug 2020 22:43:47
User entered 'None (0)'	System	21 Aug 2020 22:43:47

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T18:43:29', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f3d9d496-678f-4ae8-be88-dbc0bd066771'	System	21 Aug 2020 22:43:47
User entered 'None (0)'	System	21 Aug 2020 22:43:47

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T18:43:32', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f3d9d496-678f-4ae8-be88-dbc0bd066771'	System	21 Aug 2020 22:43:47
User entered 'None (0)'	System	21 Aug 2020 22:43:47

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T18:43:36', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f3d9d496-678f-4ae8-be88-dbc0bd066771'	System	21 Aug 2020 22:43:47
User entered 'None (0)'	System	21 Aug 2020 22:43:47

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T18:43:42', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f3d9d496-678f-4ae8-be88-dbc0bd066771'	System	21 Aug 2020 22:43:47
User entered 'No (N)'	System	21 Aug 2020 22:43:47

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-21T18:43:46', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f3d9d496-678f-4ae8-be88-dbc0bd066771'	System	21 Aug 2020 22:43:47
User entered '21 Aug 2020 18:43'	System	21 Aug 2020 22:43:47

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '21 Aug 2020 18:36'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 2'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-22T12:11:47', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '3421db10-3e05-43d2-82a2-33d6071000d8'	System	22 Aug 2020 16:12:25
User entered 'None (0)'	System	22 Aug 2020 16:12:25

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-22T12:11:56', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '3421db10-3e05-43d2-82a2-33d6071000d8'	System	22 Aug 2020 16:12:25
User entered 'None (0)'	System	22 Aug 2020 16:12:25

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-22T12:12:01', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '3421db10-3e05-43d2-82a2-33d6071000d8'	System	22 Aug 2020 16:12:25
User entered 'None (0)'	System	22 Aug 2020 16:12:25

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-22T12:12:05', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '3421db10-3e05-43d2-82a2-33d6071000d8'	System	22 Aug 2020 16:12:25
User entered 'None (0)'	System	22 Aug 2020 16:12:25

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-22T12:12:08', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '3421db10-3e05-43d2-82a2-33d6071000d8'	System	22 Aug 2020 16:12:25
User entered 'None (0)'	System	22 Aug 2020 16:12:25

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-22T12:12:11', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '3421db10-3e05-43d2-82a2-33d6071000d8'	System	22 Aug 2020 16:12:25
User entered 'None (0)'	System	22 Aug 2020 16:12:25

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-22T12:12:15', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '3421db10-3e05-43d2-82a2-33d6071000d8'	System	22 Aug 2020 16:12:25
User entered 'No (N)'	System	22 Aug 2020 16:12:25

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-22T12:12:19', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '3421db10-3e05-43d2-82a2-33d6071000d8'	System	22 Aug 2020 16:12:25
User entered '22 Aug 2020 12:12'	System	22 Aug 2020 16:12:25

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 3'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-23T13:45:23', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f27e48e6-2d2d-4e7a-a60b-1f7e9cc42032'	System	23 Aug 2020 17:46:23
User entered 'None (0)'	System	23 Aug 2020 17:46:23

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-23T13:45:33', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f27e48e6-2d2d-4e7a-a60b-1f7e9cc42032'	System	23 Aug 2020 17:46:23
User entered 'None (0)'	System	23 Aug 2020 17:46:23

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-23T13:45:47', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f27e48e6-2d2d-4e7a-a60b-1f7e9cc42032'	System	23 Aug 2020 17:46:23
User entered 'None (0)'	System	23 Aug 2020 17:46:23

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-23T13:45:52', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f27e48e6-2d2d-4e7a-a60b-1f7e9cc42032'	System	23 Aug 2020 17:46:23
User entered 'None (0)'	System	23 Aug 2020 17:46:23

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-23T13:46:01', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f27e48e6-2d2d-4e7a-a60b-1f7e9cc42032'	System	23 Aug 2020 17:46:23
User entered 'None (0)'	System	23 Aug 2020 17:46:23

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-23T13:46:04', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f27e48e6-2d2d-4e7a-a60b-1f7e9cc42032'	System	23 Aug 2020 17:46:23
User entered 'None (0)'	System	23 Aug 2020 17:46:23

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-23T13:46:16', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f27e48e6-2d2d-4e7a-a60b-1f7e9cc42032'	System	23 Aug 2020 17:46:23
User entered 'No (N)'	System	23 Aug 2020 17:46:23

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-23T13:46:21', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f27e48e6-2d2d-4e7a-a60b-1f7e9cc42032'	System	23 Aug 2020 17:46:23
User entered '23 Aug 2020 13:46'	System	23 Aug 2020 17:46:23

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 4'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-24T12:08:30', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '2c6e9f84-8197-4e6b-81ee-63cada1dea19'	System	24 Aug 2020 16:09:16
User entered 'None (0)'	System	24 Aug 2020 16:09:16

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-24T12:08:33', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '2c6e9f84-8197-4e6b-81ee-63cada1dea19'	System	24 Aug 2020 16:09:16
User entered 'None (0)'	System	24 Aug 2020 16:09:16

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-24T12:08:36', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '2c6e9f84-8197-4e6b-81ee-63cada1dea19'	System	24 Aug 2020 16:09:16
User entered 'None (0)'	System	24 Aug 2020 16:09:16

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-24T12:08:43', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '2c6e9f84-8197-4e6b-81ee-63cada1dea19'	System	24 Aug 2020 16:09:16
User entered 'None (0)'	System	24 Aug 2020 16:09:16

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-24T12:08:46', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '2c6e9f84-8197-4e6b-81ee-63cada1dea19'	System	24 Aug 2020 16:09:16
User entered 'None (0)'	System	24 Aug 2020 16:09:16

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-24T12:08:49', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '2c6e9f84-8197-4e6b-81ee-63cada1dea19'	System	24 Aug 2020 16:09:16
User entered 'None (0)'	System	24 Aug 2020 16:09:16

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-24T12:09:03', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '2c6e9f84-8197-4e6b-81ee-63cada1dea19'	System	24 Aug 2020 16:09:16
User entered 'No (N)'	System	24 Aug 2020 16:09:16

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-24T12:09:12', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '2c6e9f84-8197-4e6b-81ee-63cada1dea19'	System	24 Aug 2020 16:09:16
User entered '24 Aug 2020 12:09'	System	24 Aug 2020 16:09:16

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 5'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-25T12:14:54', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '47278f16-5b56-4881-a734-a072ffb9b594'	System	25 Aug 2020 16:15:24
User entered 'None (0)'	System	25 Aug 2020 16:15:24

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-25T12:14:58', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '47278f16-5b56-4881-a734-a072ffb9b594'	System	25 Aug 2020 16:15:24
User entered 'None (0)'	System	25 Aug 2020 16:15:24

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-25T12:15:02', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '47278f16-5b56-4881-a734-a072ffb9b594'	System	25 Aug 2020 16:15:24
User entered 'None (0)'	System	25 Aug 2020 16:15:24

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-25T12:15:06', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '47278f16-5b56-4881-a734-a072ffb9b594'	System	25 Aug 2020 16:15:24
User entered 'None (0)'	System	25 Aug 2020 16:15:24

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-25T12:15:09', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '47278f16-5b56-4881-a734-a072ffb9b594'	System	25 Aug 2020 16:15:24
User entered 'None (0)'	System	25 Aug 2020 16:15:24

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-25T12:15:11', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '47278f16-5b56-4881-a734-a072ffb9b594'	System	25 Aug 2020 16:15:24
User entered 'None (0)'	System	25 Aug 2020 16:15:24

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-25T12:15:18', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '47278f16-5b56-4881-a734-a072ffb9b594'	System	25 Aug 2020 16:15:24
User entered 'No (N)'	System	25 Aug 2020 16:15:24

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-25T12:15:21', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '47278f16-5b56-4881-a734-a072ffb9b594'	System	25 Aug 2020 16:15:24
User entered '25 Aug 2020 12:15'	System	25 Aug 2020 16:15:24

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 6'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-26T12:08:49', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '01ccc1f9-9411-42c9-82ff-9ae52ed283b0'	System	26 Aug 2020 16:09:18
User entered 'None (0)'	System	26 Aug 2020 16:09:18

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-26T12:08:52', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '01ccc1f9-9411-42c9-82ff-9ae52ed283b0'	System	26 Aug 2020 16:09:18
User entered 'None (0)'	System	26 Aug 2020 16:09:18

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-26T12:08:55', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '01ccc1f9-9411-42c9-82ff-9ae52ed283b0'	System	26 Aug 2020 16:09:18
User entered 'None (0)'	System	26 Aug 2020 16:09:18

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-26T12:08:57', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '01ccc1f9-9411-42c9-82ff-9ae52ed283b0'	System	26 Aug 2020 16:09:18
User entered 'None (0)'	System	26 Aug 2020 16:09:18

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-26T12:09:00', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '01ccc1f9-9411-42c9-82ff-9ae52ed283b0'	System	26 Aug 2020 16:09:18
User entered 'None (0)'	System	26 Aug 2020 16:09:18

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-26T12:09:04', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '01ccc1f9-9411-42c9-82ff-9ae52ed283b0'	System	26 Aug 2020 16:09:18
User entered 'None (0)'	System	26 Aug 2020 16:09:18

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-26T12:09:09', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '01ccc1f9-9411-42c9-82ff-9ae52ed283b0'	System	26 Aug 2020 16:09:18
User entered 'No (N)'	System	26 Aug 2020 16:09:18

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-26T12:09:14', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '01ccc1f9-9411-42c9-82ff-9ae52ed283b0'	System	26 Aug 2020 16:09:18
User entered '26 Aug 2020 12:09'	System	26 Aug 2020 16:09:18

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 7'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-27T12:09:03', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '83896251-df4e-411a-a4eb-e376ebee36ea'	System	27 Aug 2020 16:09:37
User entered 'None (0)'	System	27 Aug 2020 16:09:37

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-27T12:09:07', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '83896251-df4e-411a-a4eb-e376ebee36ea'	System	27 Aug 2020 16:09:37
User entered 'None (0)'	System	27 Aug 2020 16:09:37

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-27T12:09:10', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '83896251-df4e-411a-a4eb-e376ebee36ea'	System	27 Aug 2020 16:09:37
User entered 'None (0)'	System	27 Aug 2020 16:09:37

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-27T12:09:13', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '83896251-df4e-411a-a4eb-e376ebee36ea'	System	27 Aug 2020 16:09:37
User entered 'None (0)'	System	27 Aug 2020 16:09:37

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-27T12:09:16', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '83896251-df4e-411a-a4eb-e376ebee36ea'	System	27 Aug 2020 16:09:37
User entered 'None (0)'	System	27 Aug 2020 16:09:37

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-27T12:09:23', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '83896251-df4e-411a-a4eb-e376ebee36ea'	System	27 Aug 2020 16:09:37
User entered 'None (0)'	System	27 Aug 2020 16:09:37

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-27T12:09:27', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '83896251-df4e-411a-a4eb-e376ebee36ea'	System	27 Aug 2020 16:09:37
User entered 'No (N)'	System	27 Aug 2020 16:09:37

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-08-27T12:09:32', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '83896251-df4e-411a-a4eb-e376ebec36ea'	System	27 Aug 2020 16:09:37
User entered '27 Aug 2020 12:09'	System	27 Aug 2020 16:09:37

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 19:01:55

US3372209

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Yes (Y)'	Alexandra Arango (b) (4)	07 Sep 2020 15:12:05

US3372209

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered '28 Aug 2020'	Alexandra Arango (b) (4)	07 Sep 2020 15:12:05

US3372209

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	07 Sep 2020 15:12:05

US3372209

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered empty.	(b) (4) Alexandra Arango (b) (4)	07 Sep 2020 15:12:05

US3372209

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:38:40
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	07 Sep 2020 15:12:31

US3372209

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered 'I'	System	07 Sep 2020 15:12:31

US3372209

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	07 Sep 2020 15:12:51

US3372209

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered '4 Sep 2020'	(b) (4) Alexandra Arango (b) (4)	07 Sep 2020 15:12:51

US3372209

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	07 Sep 2020 15:12:51

US3372209

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered empty.	(b) (4) Alexandra Arango (b) (4)	07 Sep 2020 15:12:51
	(b) (4)	

US3372209

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:38:40
User entered 'Yes (Y)'	Alexandra Arango (b) (4)	07 Sep 2020 15:12:54

US3372209

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:54
User entered 'I'	System	07 Sep 2020 15:12:54

US3372209

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	14 Sep 2020 21:19:57

US3372209

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered '14 Sep 2020'	(b) (4) Alexandra Arango (b) (4) (b) (4)	14 Sep 2020 21:19:57

US3372209

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	14 Sep 2020 21:19:57

US3372209

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered empty.	(b) (4) Alexandra Arango (b) (4)	14 Sep 2020 21:19:57
	(b) (4)	

US3372209

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:38:40
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	14 Sep 2020 21:20:05

US3372209

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered 'I'	System	14 Sep 2020 21:20:05

US3372209

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:09:26
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	16 Nov 2020 19:10:18
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:36:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:33:37

US3372209

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:33:37

US3372209

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:33:37

US3372209

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered 'VISIT2'	System	23 Sep 2020 17:33:37

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4)	22 Oct 2020 20:41:02
	(b) (4)	

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	22 Oct 2020 20:41:02

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '23 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	22 Oct 2020 20:41:02

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '13:51'	(b) (4) Peter Jacob (b) (4) (b) (4)	22 Oct 2020 20:41:02

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered '23 Sep 2020 13:51'	System	22 Oct 2020 20:41:02

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '37.2' C	(b) (4) Peter Jacob (b) (4)	22 Oct 2020 20:41:02

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	22 Oct 2020 20:41:02

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	22 Oct 2020 20:41:02

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '64'	(b) (4) Peter Jacob (b) (4) (b) (4)	22 Oct 2020 20:41:02

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered 'bpm'	System	22 Oct 2020 20:41:02

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	22 Oct 2020 20:41:02

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered 'breaths/min'	System	22 Oct 2020 20:41:02

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '158'	(b) (4) Peter Jacob (b) (4) (b) (4)	22 Oct 2020 20:41:02

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered 'mmHg'	System	22 Oct 2020 20:41:02

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '64'	(b) (4) Peter Jacob (b) (4) (b) (4)	22 Oct 2020 20:41:02

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered 'mmHg'	System	22 Oct 2020 20:41:02

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	22 Oct 2020 20:57:48

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	22 Oct 2020 20:57:48

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '23 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	22 Oct 2020 20:57:48

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '15:12' reason for change: Data Entry Error	(b) (4)	22 Oct 2020 20:58:18
User entered '13:51'	Peter Jacob (b) (4)	22 Oct 2020 20:57:48
	(b) (4)	

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered '23 Sep 2020 15:12'	System	22 Oct 2020 20:58:18
User entered '23 Sep 2020 13:51'	System	22 Oct 2020 20:57:48

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '36.9' C reason for change: Data Entry Error	(b) (4)	22 Oct 2020 20:58:18
User entered '37.2' C	Peter Jacob (b) (4)	22 Oct 2020 20:57:48
	(b) (4)	

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	22 Oct 2020 20:57:48

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	22 Oct 2020 20:57:48

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '61' reason for change: Data Entry Error	(b) (4)	22 Oct 2020 20:58:18
User entered '64'	Peter Jacob (b) (4)	22 Oct 2020 20:57:48
	(b) (4)	

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered 'bpm'	System	22 Oct 2020 20:57:48

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	22 Oct 2020 20:57:48

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered 'breaths/min'	System	22 Oct 2020 20:57:48

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '157' reason for change: Data Entry Error	(b) (4)	
	Peter Jacob (b) (4)	22 Oct 2020 20:58:18
User entered '158'	(b) (4)	
	Peter Jacob (b) (4)	22 Oct 2020 20:57:48
	(b) (4)	

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered 'mmHg'	System	22 Oct 2020 20:57:48

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '87' reason for change: Data Entry Error	(b) (4)	22 Oct 2020 20:58:18
User entered '64'	Peter Jacob (b) (4)	22 Oct 2020 20:57:48
	(b) (4)	

US3372209

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered 'mmHg'	System	22 Oct 2020 20:57:48

US3372209

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	22 Oct 2020 21:22:54

US3372209

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered empty.	Peter Jacob (b) (4)	22 Oct 2020 21:22:54

US3372209

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:05:21

US3372209

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:05:21

US3372209

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:05:21

US3372209

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 19:05:21

US3372209

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:05:21

US3372209

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '14:39'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:05:21

US3372209

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered '23 Sep 2020 14:39'	System	23 Sep 2020 19:05:21

US3372209

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:05:21

US3372209

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered 'ONCE'	System	23 Sep 2020 19:05:21

US3372209

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 19:05:21

US3372209

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 15:04:35

US3372209

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '23 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:04:35

US3372209

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:20:23
User entered '13:59'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:04:35

US3372209

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered '23 Sep 2020 13:59'	System	23 Oct 2020 15:04:35

US3372209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:15:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:18:41
User entered '23 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:08:08

US3372209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:15:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:08:08

US3372209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:18:41
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 15:08:08

US3372209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:18:41
User entered '13:57'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:08:08

US3372209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered '23 Sep 2020 13:57'	System	23 Oct 2020 15:08:08

US3372209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:08:08

US3372209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:18:41
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 15:08:08

US3372209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:18:41
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:08:08

US3372209

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered empty.	System	23 Oct 2020 15:08:08

US3372209

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:38:40
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	02 Oct 2020 18:20:40
	(b) (4)	

US3372209

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered '1'	System	02 Oct 2020 18:20:40

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T15:12:12', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '1c60689c-05dc-44ca-b0ba-25cfe95c1642'	System	23 Sep 2020 19:12:38
User entered 'Yes (Y)'	System	23 Sep 2020 19:12:38

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T15:12:22', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '1c60689c-05dc-44ca-b0ba-25cfe95c1642'	System	23 Sep 2020 19:12:38
User entered '98.4'	System	23 Sep 2020 19:12:38

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T15:12:28', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '1c60689c-05dc-44ca-b0ba-25cfe95c1642'	System	23 Sep 2020 19:12:38
User entered 'No (N)'	System	23 Sep 2020 19:12:38

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T15:12:35', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '1c60689c-05dc-44ca-b0ba-25cfe95c1642'	System	23 Sep 2020 19:12:38
User entered '23 Sep 2020 15:12'	System	23 Sep 2020 19:12:38

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '23 Sep 2020 14:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '23 Sep 2020 17:29'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T19:06:29', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f8d743a2-8bce-4250-aec1-b8d9cc572251'	System	23 Sep 2020 23:06:52
User entered 'Yes (Y)'	System	23 Sep 2020 23:06:52

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T19:06:38', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f8d743a2-8bce-4250-aec1-b8d9cc572251'	System	23 Sep 2020 23:06:52
User entered '98.4'	System	23 Sep 2020 23:06:52

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T19:06:43', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f8d743a2-8bce-4250-aec1-b8d9cc572251'	System	23 Sep 2020 23:06:52
User entered 'No (N)'	System	23 Sep 2020 23:06:52

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T19:06:48', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'f8d743a2-8bce-4250-aec1-b8d9cc572251'	System	23 Sep 2020 23:06:52
User entered '23 Sep 2020 19:06'	System	23 Sep 2020 23:06:52

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '23 Sep 2020 18:24'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 2'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-24T12:08:01', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '17511bb1-1764-4ed4-b5aa-3ecc7b07400d'	System	24 Sep 2020 16:09:52
User entered 'Yes (Y)'	System	24 Sep 2020 16:09:52

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-24T12:08:20', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '17511bb1-1764-4ed4-b5aa-3ecc7b07400d' User entered '98.0'	System	24 Sep 2020 16:09:52
	System	24 Sep 2020 16:09:52

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-24T12:08:25', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '17511bb1-1764-4ed4-b5aa-3ecc7b07400d'	System	24 Sep 2020 16:09:52
User entered 'No (N)'	System	24 Sep 2020 16:09:52

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-24T12:08:31', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '17511bb1-1764-4ed4-b5aa-3ecc7b07400d'	System	24 Sep 2020 16:09:52
User entered '24 Sep 2020 12:08'	System	24 Sep 2020 16:09:52

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 3'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-25T12:47:32', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '310e55bf-310e-40d5-be4f-85bd618e327f'	System	25 Sep 2020 16:48:16
User entered 'Yes (Y)'	System	25 Sep 2020 16:48:16

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-25T12:47:40', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '310e55bf-310e-40d5-be4f-85bd618e327f' User entered '97.6'	System	25 Sep 2020 16:48:16
	System	25 Sep 2020 16:48:16

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-25T12:47:49', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '310e55bf-310e-40d5-be4f-85bd618e327f'	System	25 Sep 2020 16:48:16
User entered 'No (N)'	System	25 Sep 2020 16:48:16

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-25T12:48:12', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '310e55bf-310e-40d5-be4f-85bd618e327f' User entered '25 Sep 2020 12:48'	System	25 Sep 2020 16:48:16
	System	25 Sep 2020 16:48:16

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 4'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-26T13:49:52', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'e9b148fc-be81-4bc0-8c3b-285eb38402ca'	System	26 Sep 2020 17:50:22
User entered 'Yes (Y)'	System	26 Sep 2020 17:50:22

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-26T13:50:07', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'e9b148fc-be81-4bc0-8c3b-285eb38402ca'	System	26 Sep 2020 17:50:22
User entered '96.7'	System	26 Sep 2020 17:50:22

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-26T13:50:12', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'e9b148fc-be81-4bc0-8c3b-285eb38402ca'	System	26 Sep 2020 17:50:22
User entered 'No (N)'	System	26 Sep 2020 17:50:22

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-26T13:50:16', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'e9b148fc-be81-4bc0-8c3b-285eb38402ca'	System	26 Sep 2020 17:50:22
User entered '26 Sep 2020 13:50'	System	26 Sep 2020 17:50:22

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 5'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-27T14:44:22', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '430793ca-73fb-4a64-862a-bb9d8b5f7733'	System	27 Sep 2020 18:45:12
User entered 'Yes (Y)'	System	27 Sep 2020 18:45:12

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-27T14:44:58', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '430793ca-73fb-4a64-862a-bb9d8b5f7733'	System	27 Sep 2020 18:45:12
User entered '97.7'	System	27 Sep 2020 18:45:12

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-27T14:45:02', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '430793ca-73fb-4a64-862a-bb9d8b5f7733'	System	27 Sep 2020 18:45:12
User entered 'No (N)'	System	27 Sep 2020 18:45:12

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-27T14:45:08', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '430793ca-73fb-4a64-862a-bb9d8b5f7733'	System	27 Sep 2020 18:45:12
User entered '27 Sep 2020 14:45'	System	27 Sep 2020 18:45:12

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 6'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-28T14:33:47', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '719e7f27-fd3f-4942-9f0a-bd1bb421aa74'	System	28 Sep 2020 18:34:42
User entered 'Yes (Y)'	System	28 Sep 2020 18:34:42

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-28T14:34:08', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '719e7f27-fd3f-4942-9f0a-bd1bb421aa74'	System	28 Sep 2020 18:34:42
User entered '98.3'	System	28 Sep 2020 18:34:42

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-28T14:34:12', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '719e7f27-fd3f-4942-9f0a-bd1bb421aa74'	System	28 Sep 2020 18:34:42
User entered 'No (N)'	System	28 Sep 2020 18:34:42

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-28T14:34:17', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '719e7f27-fd3f-4942-9f0a-bd1bb421aa74'	System	28 Sep 2020 18:34:42
User entered '28 Sep 2020 14:34'	System	28 Sep 2020 18:34:42

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 7'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-29T13:17:47', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b4343bb7-0f5f-444e-8901-f29a061f7373'	System	29 Sep 2020 17:18:23
User entered 'Yes (Y)'	System	29 Sep 2020 17:18:23

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-29T13:18:08', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b4343bb7-0f5f-444e-8901-f29a061f7373' User entered '97.1'	System	29 Sep 2020 17:18:23
	System	29 Sep 2020 17:18:23

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-29T13:18:13', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b4343bb7-0f5f-444e-8901-f29a061f7373'	System	29 Sep 2020 17:18:23
User entered 'No (N)'	System	29 Sep 2020 17:18:23

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-29T13:18:18', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'b4343bb7-0f5f-444e-8901-f29a061f7373'	System	29 Sep 2020 17:18:23
User entered '29 Sep 2020 13:18'	System	29 Sep 2020 17:18:23

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T15:13:17', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'c669e15e-95ee-4472-9724-679631eae4e'	System	23 Sep 2020 19:13:42
User entered 'None (1)'	System	23 Sep 2020 19:13:42

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T15:13:24', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'c669e15e-95ee-4472-9724-679631eae4e'	System	23 Sep 2020 19:13:42
User entered 'No (N)'	System	23 Sep 2020 19:13:42

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T15:13:28', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'c669e15e-95ee-4472-9724-679631eae4e'	System	23 Sep 2020 19:13:42
User entered 'No (N)'	System	23 Sep 2020 19:13:42

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T15:13:35', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'c669e15e-95ee-4472-9724-679631eae4e'	System	23 Sep 2020 19:13:42
User entered 'None (1)'	System	23 Sep 2020 19:13:42

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T15:13:40', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'c669e15e-95ee-4472-9724-679631eae4e'	System	23 Sep 2020 19:13:42
User entered '23 Sep 2020 15:13'	System	23 Sep 2020 19:13:42

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '23 Sep 2020 14:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '23 Sep 2020 17:29'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T19:04:16', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'd54bf280-cca7-470c-9ff2-c8d960714b84'	System	23 Sep 2020 23:05:09
User entered 'None (1)'	System	23 Sep 2020 23:05:09

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T19:04:50', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'd54bf280-cca7-470c-9ff2-c8d960714b84'	System	23 Sep 2020 23:05:09
User entered 'No (N)'	System	23 Sep 2020 23:05:09

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T19:04:55', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'd54bf280-cca7-470c-9ff2-c8d960714b84'	System	23 Sep 2020 23:05:09
User entered 'No (N)'	System	23 Sep 2020 23:05:09

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T19:05:01', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'd54bf280-cca7-470c-9ff2-c8d960714b84'	System	23 Sep 2020 23:05:09
User entered 'None (1)'	System	23 Sep 2020 23:05:09

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T19:05:06', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'd54bf280-cca7-470c-9ff2-c8d960714b84'	System	23 Sep 2020 23:05:09
User entered '23 Sep 2020 19:05'	System	23 Sep 2020 23:05:09

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '23 Sep 2020 18:24'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 2'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-24T12:06:08', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'fc35ba9e-da9a-468f-9fa3-14a556af1ad0'	System	24 Sep 2020 16:09:53
User entered 'None (1)'	System	24 Sep 2020 16:09:53

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-24T12:06:14', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'fc35ba9e-da9a-468f-9fa3-14a556af1ad0'	System	24 Sep 2020 16:09:53
User entered 'No (N)'	System	24 Sep 2020 16:09:53

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-24T12:06:17', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'fc35ba9e-da9a-468f-9fa3-14a556af1ad0'	System	24 Sep 2020 16:09:53
User entered 'No (N)'	System	24 Sep 2020 16:09:53

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-24T12:06:26', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'fc35ba9e-da9a-468f-9fa3-14a556af1ad0'	System	24 Sep 2020 16:09:53
User entered 'None (1)'	System	24 Sep 2020 16:09:53

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-24T12:06:32', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'fc35ba9e-da9a-468f-9fa3-14a556af1ad0'	System	24 Sep 2020 16:09:53
User entered '24 Sep 2020 12:06'	System	24 Sep 2020 16:09:53

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 3'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-25T12:48:31', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '02a3d633-cea9-4eac-ba70-04922d31fdac'	System	25 Sep 2020 16:48:55
User entered 'None (1)'	System	25 Sep 2020 16:48:55

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-25T12:48:35', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '02a3d633-cea9-4eac-ba70-04922d31fdac'	System	25 Sep 2020 16:48:55
User entered 'No (N)'	System	25 Sep 2020 16:48:55

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-25T12:48:38', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '02a3d633-cea9-4eac-ba70-04922d31fdac'	System	25 Sep 2020 16:48:55
User entered 'No (N)'	System	25 Sep 2020 16:48:55

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-25T12:48:47', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '02a3d633-cea9-4eac-ba70-04922d31fdac'	System	25 Sep 2020 16:48:55
User entered 'None (1)'	System	25 Sep 2020 16:48:55

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-25T12:48:52', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '02a3d633-cea9-4eac-ba70-04922d31fdac'	System	25 Sep 2020 16:48:55
User entered '25 Sep 2020 12:48'	System	25 Sep 2020 16:48:55

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 4'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-26T13:50:25', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '114e9cd6-ac54-40a3-97d1-a4eb7faf2b5b'	System	26 Sep 2020 17:51:37
User entered 'None (1)'	System	26 Sep 2020 17:51:37

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-26T13:51:09', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '114e9cd6-ac54-40a3-97d1-a4eb7faf2b5b'	System	26 Sep 2020 17:51:37
User entered 'No (N)'	System	26 Sep 2020 17:51:37

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-26T13:51:12', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '114e9cd6-ac54-40a3-97d1-a4eb7faf2b5b'	System	26 Sep 2020 17:51:37
User entered 'No (N)'	System	26 Sep 2020 17:51:37

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-26T13:51:20', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '114e9cd6-ac54-40a3-97d1-a4eb7faf2b5b'	System	26 Sep 2020 17:51:37
User entered 'None (1)'	System	26 Sep 2020 17:51:37

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-26T13:51:34', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '114e9cd6-ac54-40a3-97d1-a4eb7faf2b5b'	System	26 Sep 2020 17:51:37
User entered '26 Sep 2020 13:51'	System	26 Sep 2020 17:51:37

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 5'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-27T14:42:47', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ee8e9ddf-d882-4f98-bad8-40f2c1b59e43'	System	27 Sep 2020 18:43:14
User entered 'None (1)'	System	27 Sep 2020 18:43:14

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-27T14:42:51', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ee8e9ddf-d882-4f98-bad8-40f2c1b59e43'	System	27 Sep 2020 18:43:14
User entered 'No (N)'	System	27 Sep 2020 18:43:14

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-27T14:42:55', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ee8e9ddf-d882-4f98-bad8-40f2c1b59e43'	System	27 Sep 2020 18:43:14
User entered 'No (N)'	System	27 Sep 2020 18:43:14

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-27T14:43:02', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ee8e9ddf-d882-4f98-bad8-40f2c1b59e43'	System	27 Sep 2020 18:43:14
User entered 'None (1)'	System	27 Sep 2020 18:43:14

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-27T14:43:10', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ee8e9ddf-d882-4f98-bad8-40f2c1b59e43'	System	27 Sep 2020 18:43:14
User entered '27 Sep 2020 14:43'	System	27 Sep 2020 18:43:14

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 6'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-28T14:32:36', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '9a40f533-3807-47d4-9af4-f83bb9502639'	System	28 Sep 2020 18:32:55
User entered 'None (1)'	System	28 Sep 2020 18:32:55

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-28T14:32:40', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '9a40f533-3807-47d4-9af4-f83bb9502639'	System	28 Sep 2020 18:32:55
User entered 'No (N)'	System	28 Sep 2020 18:32:55

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-28T14:32:44', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '9a40f533-3807-47d4-9af4-f83bb9502639'	System	28 Sep 2020 18:32:55
User entered 'No (N)'	System	28 Sep 2020 18:32:55

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-28T14:32:48', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '9a40f533-3807-47d4-9af4-f83bb9502639'	System	28 Sep 2020 18:32:55
User entered 'None (1)'	System	28 Sep 2020 18:32:55

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-28T14:32:53', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '9a40f533-3807-47d4-9af4-f83bb9502639'	System	28 Sep 2020 18:32:55
User entered '28 Sep 2020 14:32'	System	28 Sep 2020 18:32:55

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 7'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-29T13:16:42', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '766af19d-7be2-45b0-b65d-9052d951d468'	System	29 Sep 2020 17:17:06
User entered 'None (1)'	System	29 Sep 2020 17:17:06

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-29T13:16:45', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '766af19d-7be2-45b0-b65d-9052d951d468'	System	29 Sep 2020 17:17:06
User entered 'No (N)'	System	29 Sep 2020 17:17:06

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-29T13:16:48', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '766af19d-7be2-45b0-b65d-9052d951d468'	System	29 Sep 2020 17:17:06
User entered 'No (N)'	System	29 Sep 2020 17:17:06

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-29T13:16:56', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '766af19d-7be2-45b0-b65d-9052d951d468'	System	29 Sep 2020 17:17:06
User entered 'None (1)'	System	29 Sep 2020 17:17:06

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-29T13:17:01', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '766af19d-7be2-45b0-b65d-9052d951d468'	System	29 Sep 2020 17:17:06
User entered '29 Sep 2020 13:17'	System	29 Sep 2020 17:17:06

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T15:13:50', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '03f608dc-f789-4f4e-ba47-4af5bd0b6af6'	System	23 Sep 2020 19:14:26
User entered 'None (0)'	System	23 Sep 2020 19:14:26

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T15:13:56', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '03f608dc-f789-4f4e-ba47-4af5bd0b6af6'	System	23 Sep 2020 19:14:26
User entered 'None (0)'	System	23 Sep 2020 19:14:26

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T15:14:01', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '03f608dc-f789-4f4e-ba47-4af5bd0b6af6'	System	23 Sep 2020 19:14:26
User entered 'None (0)'	System	23 Sep 2020 19:14:26

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T15:14:04', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '03f608dc-f789-4f4e-ba47-4af5bd0b6af6' User entered 'None (0)'	System	23 Sep 2020 19:14:26
	System	23 Sep 2020 19:14:26

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T15:14:08', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '03f608dc-f789-4f4e-ba47-4af5bd0b6af6'	System	23 Sep 2020 19:14:26
User entered 'None (0)'	System	23 Sep 2020 19:14:26

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T15:14:11', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '03f608dc-f789-4f4e-ba47-4af5bd0b6af6'	System	23 Sep 2020 19:14:26
User entered 'None (0)'	System	23 Sep 2020 19:14:26

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T15:14:18', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '03f608dc-f789-4f4e-ba47-4af5bd0b6af6'	System	23 Sep 2020 19:14:26
User entered 'No (N)'	System	23 Sep 2020 19:14:26

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T15:14:23', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '03f608dc-f789-4f4e-ba47-4af5bd0b6af6'	System	23 Sep 2020 19:14:26
User entered '23 Sep 2020 15:14'	System	23 Sep 2020 19:14:26

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '23 Sep 2020 14:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '23 Sep 2020 17:29'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T19:05:16', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'be371a7d-435b-4829-b853-e665d425ef2f' User entered 'None (0)'	System	23 Sep 2020 23:05:46
	System	23 Sep 2020 23:05:46

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T19:05:20', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'be371a7d-435b-4829-b853-e665d425ef2f' User entered 'None (0)'	System	23 Sep 2020 23:05:46
	System	23 Sep 2020 23:05:46

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T19:05:23', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'be371a7d-435b-4829-b853-e665d425ef2f' User entered 'None (0)'	System	23 Sep 2020 23:05:46
	System	23 Sep 2020 23:05:46

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T19:05:26', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'be371a7d-435b-4829-b853-e665d425ef2f' User entered 'None (0)'	System	23 Sep 2020 23:05:46
	System	23 Sep 2020 23:05:46

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T19:05:30', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'be371a7d-435b-4829-b853-e665d425ef2f' User entered 'None (0)'	System	23 Sep 2020 23:05:46
	System	23 Sep 2020 23:05:46

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T19:05:33', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'be371a7d-435b-4829-b853-e665d425ef2f' User entered 'None (0)'	System	23 Sep 2020 23:05:46
	System	23 Sep 2020 23:05:46

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T19:05:37', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'be371a7d-435b-4829-b853-e665d425ef2f'	System	23 Sep 2020 23:05:46
User entered 'No (N)'	System	23 Sep 2020 23:05:46

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-23T19:05:43', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'be371a7d-435b-4829-b853-e665d425ef2f'	System	23 Sep 2020 23:05:46
User entered '23 Sep 2020 19:05'	System	23 Sep 2020 23:05:46

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '23 Sep 2020 18:24'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 2'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-24T12:06:44', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '12ef6040-e96d-44c0-8038-a7f4af6f5253'	System	24 Sep 2020 16:09:52
User entered 'None (0)'	System	24 Sep 2020 16:09:52

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-24T12:06:47', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '12ef6040-e96d-44c0-8038-a7f4af6f5253'	System	24 Sep 2020 16:09:52
User entered 'None (0)'	System	24 Sep 2020 16:09:52

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-24T12:06:50', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '12ef6040-e96d-44c0-8038-a7f4af6f5253'	System	24 Sep 2020 16:09:52
User entered 'None (0)'	System	24 Sep 2020 16:09:52

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-24T12:06:54', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '12ef6040-e96d-44c0-8038-a7f4af6f5253'	System	24 Sep 2020 16:09:52
User entered 'None (0)'	System	24 Sep 2020 16:09:52

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-24T12:06:57', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '12ef6040-e96d-44c0-8038-a7f4af6f5253'	System	24 Sep 2020 16:09:52
User entered 'None (0)'	System	24 Sep 2020 16:09:52

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-24T12:07:00', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '12ef6040-e96d-44c0-8038-a7f4af6f5253'	System	24 Sep 2020 16:09:52
User entered 'None (0)'	System	24 Sep 2020 16:09:52

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-24T12:07:05', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '12ef6040-e96d-44c0-8038-a7f4af6f5253'	System	24 Sep 2020 16:09:52
User entered 'No (N)'	System	24 Sep 2020 16:09:52

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-24T12:07:09', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '12ef6040-e96d-44c0-8038-a7f4af6f5253'	System	24 Sep 2020 16:09:52
User entered '24 Sep 2020 12:07'	System	24 Sep 2020 16:09:52

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 3'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-25T12:49:00', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'bf63ce5f-d854-4128-b05f-171d64177953'	System	25 Sep 2020 16:49:44
User entered 'None (0)'	System	25 Sep 2020 16:49:44

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-25T12:49:06', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'bf63ce5f-d854-4128-b05f-171d64177953'	System	25 Sep 2020 16:49:44
User entered 'None (0)'	System	25 Sep 2020 16:49:44

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-25T12:49:09', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'bf63ce5f-d854-4128-b05f-171d64177953'	System	25 Sep 2020 16:49:44
User entered 'None (0)'	System	25 Sep 2020 16:49:44

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-25T12:49:12', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'bf63ce5f-d854-4128-b05f-171d64177953'	System	25 Sep 2020 16:49:44
User entered 'None (0)'	System	25 Sep 2020 16:49:44

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-25T12:49:17', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'bf63ce5f-d854-4128-b05f-171d64177953'	System	25 Sep 2020 16:49:44
User entered 'None (0)'	System	25 Sep 2020 16:49:44

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-25T12:49:20', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'bf63ce5f-d854-4128-b05f-171d64177953'	System	25 Sep 2020 16:49:44
User entered 'None (0)'	System	25 Sep 2020 16:49:44

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-25T12:49:25', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'bf63ce5f-d854-4128-b05f-171d64177953'	System	25 Sep 2020 16:49:44
User entered 'No (N)'	System	25 Sep 2020 16:49:44

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-25T12:49:41', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'bf63ce5f-d854-4128-b05f-171d64177953'	System	25 Sep 2020 16:49:44
User entered '25 Sep 2020 12:49'	System	25 Sep 2020 16:49:44

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 4'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-26T13:51:44', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ba186f03-44ed-442e-a0c5-ac1dcdf23c5c'	System	26 Sep 2020 17:52:26
User entered 'None (0)'	System	26 Sep 2020 17:52:26

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-26T13:51:53', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ba186f03-44ed-442e-a0c5-ac1dcdf23c5c'	System	26 Sep 2020 17:52:26
User entered 'None (0)'	System	26 Sep 2020 17:52:26

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-26T13:51:58', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ba186f03-44ed-442e-a0c5-ac1dcdf23c5c'	System	26 Sep 2020 17:52:26
User entered 'None (0)'	System	26 Sep 2020 17:52:26

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-26T13:52:06', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ba186f03-44ed-442e-a0c5-ac1dcdf23c5c'	System	26 Sep 2020 17:52:26
User entered 'None (0)'	System	26 Sep 2020 17:52:26

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-26T13:52:11', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ba186f03-44ed-442e-a0c5-ac1dcdf23c5c'	System	26 Sep 2020 17:52:26
User entered 'None (0)'	System	26 Sep 2020 17:52:26

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-26T13:52:14', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ba186f03-44ed-442e-a0c5-ac1dcdf23c5c'	System	26 Sep 2020 17:52:26
User entered 'None (0)'	System	26 Sep 2020 17:52:26

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-26T13:52:19', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ba186f03-44ed-442e-a0c5-ac1dcdf23c5c'	System	26 Sep 2020 17:52:26
User entered 'No (N)'	System	26 Sep 2020 17:52:26

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-26T13:52:24', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ba186f03-44ed-442e-a0c5-ac1dcdf23c5c'	System	26 Sep 2020 17:52:26
User entered '26 Sep 2020 13:52'	System	26 Sep 2020 17:52:26

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 5'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-27T14:43:18', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '2318c12a-48c7-489f-92dc-1a9884784e44'	System	27 Sep 2020 18:43:51
User entered 'None (0)'	System	27 Sep 2020 18:43:51

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-27T14:43:26', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '2318c12a-48c7-489f-92dc-1a9884784e44'	System	27 Sep 2020 18:43:51
User entered 'None (0)'	System	27 Sep 2020 18:43:51

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-27T14:43:30', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '2318c12a-48c7-489f-92dc-1a9884784e44'	System	27 Sep 2020 18:43:51
User entered 'None (0)'	System	27 Sep 2020 18:43:51

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-27T14:43:34', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '2318c12a-48c7-489f-92dc-1a9884784e44'	System	27 Sep 2020 18:43:51
User entered 'None (0)'	System	27 Sep 2020 18:43:51

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-27T14:43:37', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '2318c12a-48c7-489f-92dc-1a9884784e44'	System	27 Sep 2020 18:43:51
User entered 'None (0)'	System	27 Sep 2020 18:43:51

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-27T14:43:40', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '2318c12a-48c7-489f-92dc-1a9884784e44'	System	27 Sep 2020 18:43:51
User entered 'None (0)'	System	27 Sep 2020 18:43:51

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-27T14:43:44', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '2318c12a-48c7-489f-92dc-1a9884784e44'	System	27 Sep 2020 18:43:51
User entered 'No (N)'	System	27 Sep 2020 18:43:51

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-27T14:43:49', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '2318c12a-48c7-489f-92dc-1a9884784e44'	System	27 Sep 2020 18:43:51
User entered '27 Sep 2020 14:43'	System	27 Sep 2020 18:43:51

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 6'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-28T14:33:00', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '7f243a20-2d99-48c7-ba37-6ad05993a551'	System	28 Sep 2020 18:33:30
User entered 'None (0)'	System	28 Sep 2020 18:33:30

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-28T14:33:03', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '7f243a20-2d99-48c7-ba37-6ad05993a551'	System	28 Sep 2020 18:33:30
User entered 'None (0)'	System	28 Sep 2020 18:33:30

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-28T14:33:07', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '7f243a20-2d99-48c7-ba37-6ad05993a551'	System	28 Sep 2020 18:33:30
User entered 'None (0)'	System	28 Sep 2020 18:33:30

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-28T14:33:12', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '7f243a20-2d99-48c7-ba37-6ad05993a551'	System	28 Sep 2020 18:33:30
User entered 'None (0)'	System	28 Sep 2020 18:33:30

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-28T14:33:15', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '7f243a20-2d99-48c7-ba37-6ad05993a551'	System	28 Sep 2020 18:33:30
User entered 'None (0)'	System	28 Sep 2020 18:33:30

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-28T14:33:18', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '7f243a20-2d99-48c7-ba37-6ad05993a551'	System	28 Sep 2020 18:33:30
User entered 'None (0)'	System	28 Sep 2020 18:33:30

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-28T14:33:22', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '7f243a20-2d99-48c7-ba37-6ad05993a551'	System	28 Sep 2020 18:33:30
User entered 'No (N)'	System	28 Sep 2020 18:33:30

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-28T14:33:26', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '7f243a20-2d99-48c7-ba37-6ad05993a551'	System	28 Sep 2020 18:33:30
User entered '28 Sep 2020 14:33'	System	28 Sep 2020 18:33:30

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	23 Sep 2020 19:05:21
User entered 'Day 7'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-29T13:17:10', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ee0f8cc5-cd55-46c7-83fd-6d3ba6877044'	System	29 Sep 2020 17:17:38
User entered 'None (0)'	System	29 Sep 2020 17:17:38

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-29T13:17:13', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ee0f8cc5-cd55-46c7-83fd-6d3ba6877044'	System	29 Sep 2020 17:17:38
User entered 'None (0)'	System	29 Sep 2020 17:17:38

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-29T13:17:17', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ee0f8cc5-cd55-46c7-83fd-6d3ba6877044'	System	29 Sep 2020 17:17:38
User entered 'None (0)'	System	29 Sep 2020 17:17:38

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-29T13:17:21', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ee0f8cc5-cd55-46c7-83fd-6d3ba6877044'	System	29 Sep 2020 17:17:38
User entered 'None (0)'	System	29 Sep 2020 17:17:38

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-29T13:17:25', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ee0f8cc5-cd55-46c7-83fd-6d3ba6877044'	System	29 Sep 2020 17:17:38
User entered 'None (0)'	System	29 Sep 2020 17:17:38

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-29T13:17:27', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ee0f8cc5-cd55-46c7-83fd-6d3ba6877044'	System	29 Sep 2020 17:17:38
User entered 'None (0)'	System	29 Sep 2020 17:17:38

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-29T13:17:31', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ee0f8cc5-cd55-46c7-83fd-6d3ba6877044'	System	29 Sep 2020 17:17:38
User entered 'No (N)'	System	29 Sep 2020 17:17:38

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-09-29T13:17:36', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ee0f8cc5-cd55-46c7-83fd-6d3ba6877044'	System	29 Sep 2020 17:17:38
User entered '29 Sep 2020 13:17'	System	29 Sep 2020 17:17:38

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 19:05:21

US3372209

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 19:05:21

US3372209

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	02 Oct 2020 18:21:14

US3372209

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
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)	13 Nov 2020 17:21:06
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 'per CRA window was based off of visit 1 date before new amendment' (Site from System).	Peter Jacob (b) (4) (b) (4)	12 Nov 2020 21:35:19
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	02 Oct 2020 18:21:14
User entered '25 Sep 2020'	Danielle Theodore (b) (4) (b) (4)	02 Oct 2020 18:21:14

US3372209

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	02 Oct 2020 18:21:14
	(b) (4)	

US3372209

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	02 Oct 2020 18:21:14

US3372209

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:38:40
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	02 Oct 2020 18:21:54
	(b) (4)	

US3372209

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered 'I'	System	02 Oct 2020 18:21:54

US3372209

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	02 Oct 2020 18:22:10
	(b) (4)	

US3372209

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 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)	13 Nov 2020 17:19:59
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'per CRA window was based off of visit 1 date before new amendment' (Site from System).	Peter Jacob (b) (4) (b) (4)	12 Nov 2020 21:35:33
User entered '02 Oct 2020' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	12 Nov 2020 21:35:30
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	02 Oct 2020 18:22:10
User entered '2 Oct 2020'	Danielle Theodore (b) (4) (b) (4)	02 Oct 2020 18:22:10

US3372209

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	02 Oct 2020 18:22:10
	(b) (4)	

US3372209

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered empty.	(b) (4) Danielle Theodore (b) (4)	02 Oct 2020 18:22:10
	(b) (4)	

US3372209

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:38:40
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	02 Oct 2020 18:23:05
	(b) (4)	

US3372209

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered 'I'	System	02 Oct 2020 18:23:05

US3372209

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	09 Oct 2020 21:16:18

US3372209

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 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)	13 Nov 2020 17:19:52
User closed query 'Per CDM Requery-Response noted,however,still Safety Call Day 50 'Date of Contact or Contact Attempt' 9 oct 2020 is less than 21 days or greater than 24 days after Visit 2 Treatment Date 23 sep 2020 on the Exposure Form. Please review and reconcile, or clarify' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 17:19:49
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'per CRA window was based off of visit 1 date before new amendment' (Site from System).	Peter Jacob (b) (4) (b) (4)	13 Nov 2020 15:42:43
Query 'Per CDM Requery-Response noted,however,still Safety Call Day 50 'Date of Contact or Contact Attempt' 9 oct 2020 is less than 21 days or greater than 24 days after Visit 2 Treatment Date 23 sep 2020 on the Exposure Form. Please review and reconcile, or clarify' answered with 'per CRA window was based off of visit 1 date before new amendment' (Site from DM).	Peter Jacob (b) (4) (b) (4)	13 Nov 2020 15:42:37
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	13 Nov 2020 15:42:32
User entered '09 Oct 2020' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	13 Nov 2020 15:42:32

US3372209

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per CDM Requery-Response noted,however,still Safety Call Day 50 'Date of Contact or Contact Attempt' 9 oct 2020 is less than 21 days or greater than 24 days after Visit 2 Treatment Date 23 sep 2020 on the Exposure Form. Please review and reconcile, or clarify' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:19:55
Query 'Per CDM Requery-Response noted,however,still Safety Call Day 50 'Date of Contact or Contact Attempt' 9 oct 2020 is less than 21 days or greater than 24 days after Visit 2 Treatment Date 21 sep 2020 on the Exposure Form. Please review and reconcile, or clarify.' canceled (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:19:46
User opened query 'Per CDM Requery-Response noted,however,still Safety Call Day 50 'Date of Contact or Contact Attempt' 9 oct 2020 is less than 21 days or greater than 24 days after Visit 2 Treatment Date 21 sep 2020 on the Exposure Form. Please review and reconcile, or clarify.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:19:24
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 11:18:56
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Phone visit completed within window per protocol.' (Site from System).	Alexandra Arango (b) (4) (b) (4)	09 Oct 2020 21:16:32
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Oct 2020 21:16:18
User entered '9 Oct 2020'	Alexandra Arango (b) (4) (b) (4)	09 Oct 2020 21:16:18

US3372209

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	09 Oct 2020 21:16:18

US3372209

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered empty.	(b) (4) Alexandra Arango (b) (4)	09 Oct 2020 21:16:18
	(b) (4)	

US3372209

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:38:40
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	09 Oct 2020 21:16:38

US3372209

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered 'I'	System	09 Oct 2020 21:16:38

US3372209

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:00:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:00:42

US3372209

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:00:57
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:00:42

US3372209

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:00:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 17:00:42

US3372209

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered 'VISIT3'	System	19 Oct 2020 17:00:42

US3372209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:00:57
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:09:24

US3372209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:00:57
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:09:24

US3372209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:00:57
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:09:24

US3372209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered empty.	System	23 Oct 2020 15:09:24

US3372209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:00:57
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:09:24

US3372209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:00:57
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:09:24

US3372209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:00:57
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:09:24

US3372209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:00:57
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:09:24

US3372209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered empty.	System	23 Oct 2020 15:09:24

US3372209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:00:57
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:09:24

US3372209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered empty.	System	23 Oct 2020 15:09:24

US3372209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:00:57
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:09:24

US3372209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered empty.	System	23 Oct 2020 15:09:24

US3372209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:00:57
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:09:24

US3372209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered empty.	System	23 Oct 2020 15:09:24

US3372209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13

US3372209

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13

US3372209

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:00:57
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:09:31

US3372209

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:00:57
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 15:09:31

US3372209

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:00:57
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 15:20:16

US3372209

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:00:57
User entered '19 Oct 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:20:16

US3372209

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:00:57
User entered '12:55'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:20:16

US3372209

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered '19 Oct 2020 12:55'	System	23 Oct 2020 15:20:16

US3372209

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:38:40
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:20:23

US3372209

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered '1'	System	23 Oct 2020 15:20:23

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 64'	System	21 Aug 2020 19:01:55

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-10-22T16:44:40', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '25ab201f-dd81-4a55-b02c-17fe9439f1d4'	System	22 Oct 2020 20:45:07
User entered 'No (N)'	System	22 Oct 2020 20:45:07

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-10-22T16:44:50', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '25ab201f-dd81-4a55-b02c-17fe9439f1d4'	System	22 Oct 2020 20:45:07
User entered 'No (N)'	System	22 Oct 2020 20:45:07

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-10-22T16:44:58', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '25ab201f-dd81-4a55-b02c-17fe9439f1d4'	System	22 Oct 2020 20:45:07
User entered '22 Oct 2020 16:44:58'	System	22 Oct 2020 20:45:07

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 19:01:55

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 71'	System	21 Aug 2020 19:01:55

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-10-28T13:35:33', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'a9d24b21-07f5-402f-a0e1-d32383007dc2'	System	28 Oct 2020 17:36:12
User entered 'No (N)'	System	28 Oct 2020 17:36:12

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-10-28T13:35:49', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'a9d24b21-07f5-402f-a0e1-d32383007dc2'	System	28 Oct 2020 17:36:12
User entered 'No (N)'	System	28 Oct 2020 17:36:12

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-10-28T13:36:07', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'a9d24b21-07f5-402f-a0e1-d32383007dc2'	System	28 Oct 2020 17:36:12
User entered '28 Oct 2020 13:36:07'	System	28 Oct 2020 17:36:12

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 19:01:55

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 78'	System	21 Aug 2020 19:01:55

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-11-04T10:51:41', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '14ab70d3-2e43-47b1-b6fd-f1c8e7e7231c'	System	04 Nov 2020 15:52:07
User entered 'No (N)'	System	04 Nov 2020 15:52:07

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-11-04T10:51:54', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '14ab70d3-2e43-47b1-b6fd-f1c8e7e7231c'	System	04 Nov 2020 15:52:07
User entered 'No (N)'	System	04 Nov 2020 15:52:07

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-11-04T10:52:01', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '14ab70d3-2e43-47b1-b6fd-f1c8e7e7231c'	System	04 Nov 2020 15:52:07
User entered '04 Nov 2020 10:52:01'	System	04 Nov 2020 15:52:07

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 19:01:55

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered 'Day 92'	System	21 Aug 2020 19:01:55

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-11-18T09:52:32', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'e4bbaa5e-8656-48ca-94f1-2a16f13ccf57'	System	18 Nov 2020 14:52:58
User entered 'No (N)'	System	18 Nov 2020 14:52:58

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-11-18T09:52:45', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'e4bbaa5e-8656-48ca-94f1-2a16f13ccf57'	System	18 Nov 2020 14:52:58
User entered 'No (N)'	System	18 Nov 2020 14:52:58

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-11-18T09:52:54', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'e4bbaa5e-8656-48ca-94f1-2a16f13ccf57'	System	18 Nov 2020 14:52:58
User entered '18 Nov 2020 09:52:54'	System	18 Nov 2020 14:52:58

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 19:01:55

US3372209

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:57:18
Data entry locked.	System	21 Aug 2020 19:01:55
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 19:01:55

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2020-12-02T15:52:04', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ad143527-932b-4cec-9e8b-9a7a1284bb63'	System	02 Dec 2020 20:52:27
User entered 'No (N)'	System	02 Dec 2020 20:52:27

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2020-12-02T15:52:16', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ad143527-932b-4cec-9e8b-9a7a1284bb63'	System	02 Dec 2020 20:52:27
User entered 'No (N)'	System	02 Dec 2020 20:52:27

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-12-02T15:52:23', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'ad143527-932b-4cec-9e8b-9a7a1284bb63'	System	02 Dec 2020 20:52:27
User entered '02 Dec 2020 15:52:23'	System	02 Dec 2020 20:52:27

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2020-12-06T10:17:22', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '0a54c0dd-4f96-41a7-84f7-f1f60356eb96'	System	06 Dec 2020 15:17:49
User entered 'No (N)'	System	06 Dec 2020 15:17:49

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2020-12-06T10:17:38', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '0a54c0dd-4f96-41a7-84f7-f1f60356eb96'	System	06 Dec 2020 15:17:49
User entered 'No (N)'	System	06 Dec 2020 15:17:49

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-12-06T10:17:45', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '0a54c0dd-4f96-41a7-84f7-f1f60356eb96'	System	06 Dec 2020 15:17:49
User entered '06 Dec 2020 10:17:45'	System	06 Dec 2020 15:17:49

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2020-12-14T10:26:47', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '663269d9-2b9c-441f-b03d-e855b93e8b15'	System	14 Dec 2020 15:27:04
User entered 'No (N)'	System	14 Dec 2020 15:27:04

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2020-12-14T10:26:52', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '663269d9-2b9c-441f-b03d-e855b93e8b15'	System	14 Dec 2020 15:27:04
User entered 'No (N)'	System	14 Dec 2020 15:27:04

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-12-14T10:26:59', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '663269d9-2b9c-441f-b03d-e855b93e8b15'	System	14 Dec 2020 15:27:04
User entered '14 Dec 2020 10:26:59'	System	14 Dec 2020 15:27:04

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2020-12-20T12:09:31', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '71eb9939-adbe-4b98-9963-90a44c40b4f8'	System	20 Dec 2020 17:10:48
User entered 'No (N)'	System	20 Dec 2020 17:10:48

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2020-12-20T12:09:38', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '71eb9939-adbe-4b98-9963-90a44c40b4f8'	System	20 Dec 2020 17:10:48
User entered 'No (N)'	System	20 Dec 2020 17:10:48

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-12-20T12:10:41', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '71eb9939-adbe-4b98-9963-90a44c40b4f8'	System	20 Dec 2020 17:10:48
User entered '20 Dec 2020 12:10:41'	System	20 Dec 2020 17:10:48

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2020-12-27T07:50:13', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '798437b0-d446-4b7c-adf1-7fa601b565e3'	System	27 Dec 2020 12:50:27
User entered 'No (N)'	System	27 Dec 2020 12:50:27

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2020-12-27T07:50:19', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '798437b0-d446-4b7c-adf1-7fa601b565e3'	System	27 Dec 2020 12:50:27
User entered 'No (N)'	System	27 Dec 2020 12:50:27

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2020-12-27T07:50:24', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '798437b0-d446-4b7c-adf1-7fa601b565e3'	System	27 Dec 2020 12:50:27
User entered '27 Dec 2020 07:50:24'	System	27 Dec 2020 12:50:27

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2021-01-03T12:26:39', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'fcb756af-c1ed-45fc-a24a-77ed5b745fce'	System	03 Jan 2021 17:26:59
User entered 'No (N)'	System	03 Jan 2021 17:26:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2021-01-03T12:26:48', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'fcb756af-c1ed-45fc-a24a-77ed5b745fce'	System	03 Jan 2021 17:26:59
User entered 'No (N)'	System	03 Jan 2021 17:26:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-01-03T12:26:55', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'fcb756af-c1ed-45fc-a24a-77ed5b745fce'	System	03 Jan 2021 17:26:59
User entered '03 Jan 2021 12:26:55'	System	03 Jan 2021 17:26:59

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2021-01-10T07:59:54', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '66581ffc-af46-4ff0-962e-7aec5e2dd126'	System	10 Jan 2021 13:00:09
User entered 'No (N)'	System	10 Jan 2021 13:00:09

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2021-01-10T07:59:58', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '66581ffc-af46-4ff0-962e-7aec5e2dd126'	System	10 Jan 2021 13:00:09
User entered 'No (N)'	System	10 Jan 2021 13:00:09

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-01-10T08:00:04', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '66581ffc-af46-4ff0-962e-7aec5e2dd126'	System	10 Jan 2021 13:00:09
User entered '10 Jan 2021 08:00:04'	System	10 Jan 2021 13:00:09

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2021-01-17T15:37:48', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '938b37e9-9030-4ef1-84ea-05ba71fcfab4'	System	17 Jan 2021 20:38:03
User entered 'No (N)'	System	17 Jan 2021 20:38:03

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2021-01-17T15:37:53', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '938b37e9-9030-4ef1-84ea-05ba71fcfab4'	System	17 Jan 2021 20:38:03
User entered 'No (N)'	System	17 Jan 2021 20:38:03

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-01-17T15:37:58', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '938b37e9-9030-4ef1-84ea-05ba71fcfab4'	System	17 Jan 2021 20:38:03
User entered '17 Jan 2021 15:37:58'	System	17 Jan 2021 20:38:03

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2021-01-24T10:04:07', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '35b28926-3fd2-47cf-85af-6b59ad7ca5c6'	System	24 Jan 2021 15:04:27
User entered 'No (N)'	System	24 Jan 2021 15:04:27

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2021-01-24T10:04:17', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '35b28926-3fd2-47cf-85af-6b59ad7ca5c6'	System	24 Jan 2021 15:04:27
User entered 'No (N)'	System	24 Jan 2021 15:04:27

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-01-24T10:04:23', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '35b28926-3fd2-47cf-85af-6b59ad7ca5c6'	System	24 Jan 2021 15:04:27
User entered '24 Jan 2021 10:04:23'	System	24 Jan 2021 15:04:27

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2021-01-31T12:34:51', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'd8ed346b-11d5-4aae-b8f3-ab6443de5ccf'	System	31 Jan 2021 17:35:05
User entered 'No (N)'	System	31 Jan 2021 17:35:05

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2021-01-31T12:34:56', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'd8ed346b-11d5-4aae-b8f3-ab6443de5ccf'	System	31 Jan 2021 17:35:05
User entered 'No (N)'	System	31 Jan 2021 17:35:05

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-01-31T12:35:01', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'd8ed346b-11d5-4aae-b8f3-ab6443de5ccf'	System	31 Jan 2021 17:35:05
User entered '31 Jan 2021 12:35:01'	System	31 Jan 2021 17:35:05

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2021-02-15T08:35:22', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '33977777-68e3-41da-a444-3e49c3472d7f'	System	15 Feb 2021 13:36:23
User entered 'Yes (Y)'	System	15 Feb 2021 13:36:23

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2021-02-15T08:35:30', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '33977777-68e3-41da-a444-3e49c3472d7f' User entered 'No (N)'	System	15 Feb 2021 13:36:23

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-02-15T08:35:37', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '33977777-68e3-41da-a444-3e49c3472d7f'	System	15 Feb 2021 13:36:23
User entered 'No (N)'	System	15 Feb 2021 13:36:23

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-02-15T08:35:47', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '33977777-68e3-41da-a444-3e49c3472d7f'	System	15 Feb 2021 13:36:23
User entered 'Yes (Y)'	System	15 Feb 2021 13:36:23

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-02-15T08:36:04', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '33977777-68e3-41da-a444-3e49c3472d7f'	System	15 Feb 2021 13:36:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Feb 2021 13:36:23

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-02-15T08:36:11', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '33977777-68e3-41da-a444-3e49c3472d7f'	System	15 Feb 2021 13:36:23
User entered '15 Feb 2021 08:36:11'	System	15 Feb 2021 13:36:23

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2021-02-21T11:10:12', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'cf38a80b-7854-4c1d-9b73-467db8be8475'	System	21 Feb 2021 16:10:28
User entered 'No (N)'	System	21 Feb 2021 16:10:28

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2021-02-21T11:10:16', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'cf38a80b-7854-4c1d-9b73-467db8be8475'	System	21 Feb 2021 16:10:28
User entered 'No (N)'	System	21 Feb 2021 16:10:28

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-02-21T11:10:22', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'cf38a80b-7854-4c1d-9b73-467db8be8475'	System	21 Feb 2021 16:10:28
User entered '21 Feb 2021 11:10:22'	System	21 Feb 2021 16:10:28

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2021-03-01T18:56:39', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'dbd4780b-3cae-46f3-aa7c-2b4f1c6b5fc5'	System	01 Mar 2021 23:57:11
User entered 'No (N)'	System	01 Mar 2021 23:57:11

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2021-03-01T18:56:43', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'dbd4780b-3cae-46f3-aa7c-2b4f1c6b5fc5'	System	01 Mar 2021 23:57:11
User entered 'No (N)'	System	01 Mar 2021 23:57:11

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-03-01T18:57:06', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'dbd4780b-3cae-46f3-aa7c-2b4f1c6b5fc5'	System	01 Mar 2021 23:57:11
User entered '01 Mar 2021 18:57:06'	System	01 Mar 2021 23:57:11

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2021-03-07T10:38:40', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '24476fc9-8768-4d27-aff5-022edbdad3eb'	System	07 Mar 2021 15:39:00
User entered 'No (N)'	System	07 Mar 2021 15:39:00

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2021-03-07T10:38:48', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '24476fc9-8768-4d27-aff5-022edbdad3eb'	System	07 Mar 2021 15:39:00
User entered 'No (N)'	System	07 Mar 2021 15:39:00

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-03-07T10:38:56', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '24476fc9-8768-4d27-aff5-022edbdad3eb'	System	07 Mar 2021 15:39:00
User entered '07 Mar 2021 10:38:56'	System	07 Mar 2021 15:39:00

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2021-03-14T13:06:37', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '81d3ed10-74e0-4d29-8e1a-93f1b5bbbe77'	System	14 Mar 2021 17:08:50
User entered 'No (N)'	System	14 Mar 2021 17:08:50

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2021-03-14T13:06:42', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '81d3ed10-74e0-4d29-8e1a-93f1b5bbbe77'	System	14 Mar 2021 17:08:50
User entered 'No (N)'	System	14 Mar 2021 17:08:50

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-03-14T13:06:49', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '81d3ed10-74e0-4d29-8e1a-93f1b5bbbe77'	System	14 Mar 2021 17:08:50
User entered '14 Mar 2021 13:06:49'	System	14 Mar 2021 17:08:50

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2021-03-21T20:39:03', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '4bab9d59-5256-4aed-8b3e-b2940323f060'	System	22 Mar 2021 00:39:23
User entered 'No (N)'	System	22 Mar 2021 00:39:23

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2021-03-21T20:39:13', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '4bab9d59-5256-4aed-8b3e-b2940323f060'	System	22 Mar 2021 00:39:23
User entered 'No (N)'	System	22 Mar 2021 00:39:23

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-03-21T20:39:19', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '4bab9d59-5256-4aed-8b3e-b2940323f060'	System	22 Mar 2021 00:39:23
User entered '21 Mar 2021 20:39:19'	System	22 Mar 2021 00:39:23

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2021-03-29T11:18:55', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '90cbfe8e-d55e-46c5-a321-764679578936'	System	13 Apr 2021 21:23:16
User entered 'No (N)'	System	13 Apr 2021 21:23:16

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2021-03-29T11:19:05', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '90cbfe8e-d55e-46c5-a321-764679578936'	System	13 Apr 2021 21:23:16
User entered 'No (N)'	System	13 Apr 2021 21:23:16

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-03-29T11:19:09', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '90cbfe8e-d55e-46c5-a321-764679578936'	System	13 Apr 2021 21:23:16
User entered '29 Mar 2021 11:19:09'	System	13 Apr 2021 21:23:16

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2021-04-13T17:24:21-04:00', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'dee502ce-e315-4822-af96-59bd147a5d15'	System	13 Apr 2021 21:24:39
User entered 'No (N)'	System	13 Apr 2021 21:24:39

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2021-04-13T17:24:27-04:00', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'dee502ce-e315-4822-af96-59bd147a5d15'	System	13 Apr 2021 21:24:39
User entered 'No (N)'	System	13 Apr 2021 21:24:39

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-04-13T17:24:34-04:00', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: 'dee502ce-e315-4822-af96-59bd147a5d15'	System	13 Apr 2021 21:24:39
User entered '13 Apr 2021 17:24:34'	System	13 Apr 2021 21:24:39

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2021-04-19T11:22:03-04:00', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '160db603-f8aa-424a-9844-e4f909da44c3'	System	19 Apr 2021 15:22:19
User entered 'No (N)'	System	19 Apr 2021 15:22:19

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2021-04-19T11:22:08-04:00', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '160db603-f8aa-424a-9844-e4f909da44c3'	System	19 Apr 2021 15:22:19
User entered 'No (N)'	System	19 Apr 2021 15:22:19

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-04-19T11:22:13-04:00', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '160db603-f8aa-424a-9844-e4f909da44c3'	System	19 Apr 2021 15:22:19
User entered '19 Apr 2021 11:22:13'	System	19 Apr 2021 15:22:19

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2021-04-25T11:40:09-04:00', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '9f5d5c90-cd67-4e53-a386-5d1f4012f940'	System	25 Apr 2021 15:40:25
User entered 'No (N)'	System	25 Apr 2021 15:40:25

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2021-04-25T11:40:14-04:00', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '9f5d5c90-cd67-4e53-a386-5d1f4012f940'	System	25 Apr 2021 15:40:25
User entered 'No (N)'	System	25 Apr 2021 15:40:25

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-04-25T11:40:19-04:00', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '9f5d5c90-cd67-4e53-a386-5d1f4012f940'	System	25 Apr 2021 15:40:25
User entered '25 Apr 2021 11:40:19'	System	25 Apr 2021 15:40:25

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (5574330ab0d7aed0)', Time: '2021-05-03T13:53:37-04:00', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '202fa358-3c0c-49ab-a61e-173d2627ff03'	System	03 May 2021 17:54:00
User entered 'No (N)'	System	03 May 2021 17:54:00

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (5574330ab0d7aed0)', Time: '2021-05-03T13:53:42-04:00', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '202fa358-3c0c-49ab-a61e-173d2627ff03'	System	03 May 2021 17:54:00
User entered 'No (N)'	System	03 May 2021 17:54:00

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-05-03T13:53:54-04:00', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '202fa358-3c0c-49ab-a61e-173d2627ff03'	System	03 May 2021 17:54:00
User entered '03 May 2021 13:53:54'	System	03 May 2021 17:54:00

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:46:17

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:46:17

US3372209

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:46:17
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:46:17

US3372209

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:15:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:59:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-03-01T18:57:19', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '38b4f619-6fca-4667-85cf-18da3ba5bcbc'	System	01 Mar 2021 23:57:29
User entered 'No (N)'	System	01 Mar 2021 23:57:29

US3372209

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:15:59

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:59:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5574330ab0d7aed0)', Time: '2021-03-01T18:57:26', User OID: 'PatientReportedOutcome (US3372209)', ODM File OID: '38b4f619-6fca-4667-85cf-18da3ba5bcbc'	System	01 Mar 2021 23:57:29
User entered '01 Mar 2021 18:57:26'	System	01 Mar 2021 23:57:29

US3372209

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	18 Nov 2020 17:20:01

US3372209

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered '18 Nov 2020'	(b) (4) Danielle Theodore (b) (4)	18 Nov 2020 17:20:01

US3372209

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	18 Nov 2020 17:20:01
	(b) (4)	

US3372209

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	18 Nov 2020 17:20:01

US3372209

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:38:40
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	18 Nov 2020 17:20:15

US3372209

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:44:13
User entered 'I'	System	18 Nov 2020 17:20:15

US3372209

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	22 Dec 2020 18:15:18

US3372209

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered '22 Dec 2020'	(b) (4) Danielle Theodore (b) (4)	22 Dec 2020 18:15:18
	(b) (4)	

US3372209

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	22 Dec 2020 18:15:18

US3372209

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	22 Dec 2020 18:15:18

US3372209

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:38:40
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	22 Dec 2020 18:15:22
	(b) (4)	

US3372209

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User entered 'I'	System	22 Dec 2020 18:15:22

US3372209

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	22 Jan 2021 15:09:06

US3372209

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered '22 Jan 2021'	(b) (4) Danielle Theodore (b) (4)	22 Jan 2021 15:09:06
	(b) (4)	

US3372209

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	22 Jan 2021 15:09:06
	(b) (4)	

US3372209

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered empty.	(b) (4) Danielle Theodore (b) (4)	22 Jan 2021 15:09:06
	(b) (4)	

US3372209

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:38:40
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	22 Jan 2021 15:09:12

US3372209

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User entered 'I'	System	22 Jan 2021 15:09:12

US3372209

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	16 Feb 2021 21:22:03

US3372209

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	17 Feb 2021 14:34:38
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'date correct as entered' (Site from System).	(b) (4) Danielle Theodore (b) (4)	16 Feb 2021 21:22:13
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	16 Feb 2021 21:22:03
User entered '16 Feb 2021'	Danielle Theodore (b) (4)	16 Feb 2021 21:22:03

US3372209

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	16 Feb 2021 21:22:03

US3372209

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	16 Feb 2021 21:22:03

US3372209

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 22:40:43
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	16 Feb 2021 21:22:26
	(b) (4)	

US3372209

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User entered 'I'	System	16 Feb 2021 21:22:26

US3372209

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:27:18

US3372209

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:27:18

US3372209

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:27:18

US3372209

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User entered 'VISIT4'	System	18 Mar 2021 16:27:18

US3372209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:29:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:17:58

US3372209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:29:04
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:17:58

US3372209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:29:04
User entered '14:06'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:17:58

US3372209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User entered '17 Mar 2021 14:06'	System	30 Mar 2021 20:17:58

US3372209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:29:04
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:17:58

US3372209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:29:04
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:17:58

US3372209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:29:04
User entered 'Forehead'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:17:58

US3372209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:29:04
User entered '55'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:17:58

US3372209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User entered 'bpm'	System	30 Mar 2021 20:17:58

US3372209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:29:04
User entered '16'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:17:58

US3372209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User entered 'breaths/min'	System	30 Mar 2021 20:17:58

US3372209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:29:04
User entered '143'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:17:58

US3372209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User entered 'mmHg'	System	30 Mar 2021 20:17:58

US3372209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:29:04
User entered '70'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:17:58

US3372209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User entered 'mmHg'	System	30 Mar 2021 20:17:58

US3372209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09

US3372209

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09

US3372209

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:27:21

US3372209

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:27:21

US3372209

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:27:35

US3372209

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:27:35

US3372209

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered '14:20'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:27:35

US3372209

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User entered '17 Mar 2021 14:20'	System	18 Mar 2021 16:27:35

US3372209

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 16:27:39

US3372209

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:24:09
User entered 'I'	System	18 Mar 2021 16:27:39

US3372209

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:10
	(b) (4)	
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	21 Apr 2021 15:08:09
	(b) (4)	

US3372209

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:10
	(b) (4)	
User entered '21 Apr 2021'	Danielle Theodore (b) (4)	21 Apr 2021 15:08:09
	(b) (4)	

US3372209

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	21 Apr 2021 15:08:09

US3372209

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:10
User entered empty.	(b) (4)	
	Danielle Theodore (b) (4)	21 Apr 2021 15:08:09
	(b) (4)	

US3372209

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	22 Apr 2021 16:38:10
	(b) (4)	
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	21 Apr 2021 15:08:21
	(b) (4)	

US3372209

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 15:08:21

US3372209

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

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:00:29

US3372209

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

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:13:15
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:00:29

US3372209

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

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:13:15
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:00:29

US3372209

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

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'UNBLND_DECIDE'	System	21 Jan 2021 20:00:29

US3372209

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:54:03
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:00:52

US3372209

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	12 Apr 2021 21:32:02
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:18:22
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:30:33

US3372209

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:54:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:00:52

US3372209

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 05:45:53
User signature succeeded.	Mira Baron (b) (4)	12 Apr 2021 21:32:02
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 18:18:26
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	12 Apr 2021 18:18:22
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:10:58
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:30:33

US3372209

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:54:03
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:00:52

US3372209

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:54:03
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:00:52

US3372209

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:54:03
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:00:52

US3372209

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:54:03
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:00:52

US3372209

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:54:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:00:52

US3372209

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered '1'	System	21 Jan 2021 20:00:52

US3372209

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'I'	System	21 Jan 2021 20:00:52

US3372209

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered empty.	System	21 Jan 2021 20:02:52
DataPoint set to visible.	System	21 Jan 2021 20:00:52

US3372209

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered empty.	System	21 Jan 2021 20:02:52
DataPoint set to visible.	System	21 Jan 2021 20:00:52

US3372209

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '13:45'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered '19 Jan 2021 13:45'	System	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '62'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'bpm'	System	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '17'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'breaths/min'	System	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '181'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'mmHg'	System	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '74'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'mmHg'	System	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered empty.	System	21 Jan 2021 20:02:52
DataPoint set to visible.	System	21 Jan 2021 20:00:52

US3372209

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '15:00'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered '19 Jan 2021 15:00'	System	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered 'FPREHEAD'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '62'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'bpm'	System	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '17'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'breaths/min'	System	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '179'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'mmHg'	System	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '77'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:52

US3372209

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'mmHg'	System	21 Jan 2021 20:02:52

US3372209

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:07:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:58

US3372209

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:07:18
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:02:58

US3372209

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:43:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:03:15

US3372209

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:43:17
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:03:15

US3372209

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:43:17
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:03:15

US3372209

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'mRNA-1273'	System	21 Jan 2021 20:03:15
DataPoint set to visible.	System	21 Jan 2021 20:00:52

US3372209

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:43:17
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:03:15

US3372209

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:43:17
User entered '14:28'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:03:15

US3372209

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered '19 Jan 2021 14:28'	System	21 Jan 2021 20:03:15

US3372209

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:43:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:03:15

US3372209

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'ONCE'	System	21 Jan 2021 20:03:15

US3372209

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'INTRAMUSCULAR'	System	21 Jan 2021 20:03:15

US3372209

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:03:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:01:05

US3372209

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:03:01
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:01:05

US3372209

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:03:01
User entered '13:32'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:01:05

US3372209

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered '19 Jan 2021 13:32'	System	21 Jan 2021 20:01:05

US3372209

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:38:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:01:17

US3372209

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:38:14
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:01:17

US3372209

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:38:14
User entered '13:29'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:01:17

US3372209

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered '19 Jan 2021 13:29'	System	21 Jan 2021 20:01:17

US3372209

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

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:38:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:01:21

US3372209

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

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'I'	System	21 Jan 2021 20:01:21

US3372209

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	26 Jan 2021 19:27:16

US3372209

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered '26 Jan 2021'	(b) (4) Danielle Theodore (b) (4)	26 Jan 2021 19:27:16

US3372209

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	26 Jan 2021 19:27:16
	(b) (4)	

US3372209

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:34:49
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	26 Jan 2021 19:27:16

US3372209

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:38:40
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	26 Jan 2021 19:27:37

US3372209

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'I'	System	26 Jan 2021 19:27:37

US3372209

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered '1'	System	26 Jan 2021 19:27:37
DataPoint set to visible.	System	26 Jan 2021 19:27:37

US3372209

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:13:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:18:16

US3372209

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:13:15
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:18:16

US3372209

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:13:15
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:18:16

US3372209

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'OLD29'	System	16 Feb 2021 16:18:16

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '12:16'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered '15 Feb 2021 12:16'	System	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '59'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'bpm'	System	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '16'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'breaths/min'	System	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '158'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'mmHg'	System	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '81'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'mmHg'	System	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '13:22'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered '15 Feb 2021 13:22'	System	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '52'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'bpm'	System	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '14'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'breaths/min'	System	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '150'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'mmHg'	System	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:45:57
User entered '82'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'mmHg'	System	16 Feb 2021 16:19:43

US3372209

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:07:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:52

US3372209

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:07:18
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:19:52

US3372209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:43:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:20:17

US3372209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:43:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:20:17

US3372209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:43:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:20:17

US3372209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'mRNA-1273'	System	16 Feb 2021 16:20:17
DataPoint set to visible.	System	26 Jan 2021 19:27:37

US3372209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:43:17
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:20:17

US3372209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:43:17
User entered '12:45'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:20:17

US3372209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered '15 Feb 2021 12:45'	System	16 Feb 2021 16:20:17

US3372209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:43:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:20:17

US3372209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'ONCE'	System	16 Feb 2021 16:20:17

US3372209

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'INTRAMUSCULAR'	System	16 Feb 2021 16:20:17

US3372209

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:38:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:20:34

US3372209

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'I'	System	16 Feb 2021 16:20:34

US3372209

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:22:35
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	15 Mar 2021 18:00:32

US3372209

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:22:35
User entered '22 Feb 2021'	(b) (4) Danielle Theodore (b) (4)	15 Mar 2021 18:00:32
	(b) (4)	

US3372209

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:22:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	15 Mar 2021 18:00:32

US3372209

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:22:35
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	15 Mar 2021 18:00:32

US3372209

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:22:35
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	15 Mar 2021 18:00:37
	(b) (4)	

US3372209

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'I'	System	15 Mar 2021 18:00:37

US3372209

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:49:57

US3372209

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:49:57

US3372209

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:49:57

US3372209

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'OLD57'	System	18 Mar 2021 15:49:57

US3372209

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User closed query 'Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' (Site from DM). Query 'Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' answered with 'Data updated.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 15:31:03
User opened query 'Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 20:18:13
User opened query 'Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	28 Mar 2021 10:43:34
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 15:50:29

US3372209

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:50:29

US3372209

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered '14:06'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:50:29

US3372209

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered '17 Mar 2021 14:06'	System	18 Mar 2021 15:50:29

US3372209

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:50:29

US3372209

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:50:29

US3372209

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered 'forehead'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:50:29

US3372209

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered '55'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:50:29

US3372209

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'bpm'	System	18 Mar 2021 15:50:29

US3372209

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered '16'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:50:29

US3372209

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'breaths/min'	System	18 Mar 2021 15:50:29

US3372209

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered '143'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:50:29

US3372209

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'mmHg'	System	18 Mar 2021 15:50:29

US3372209

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered '70'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:50:29

US3372209

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered 'mmHg'	System	18 Mar 2021 15:50:29

US3372209

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50

US3372209

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50

US3372209

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:50:36

US3372209

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:50:36

US3372209

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:50:51

US3372209

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:50:51

US3372209

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User signature succeeded.	Mira Baron (b) (4)	19 Mar 2021 15:33:47
User entered '14:20'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:50:51

US3372209

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:50
User entered '17 Mar 2021 14:20'	System	18 Mar 2021 15:50:51

US3372209

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:15:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:15
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 180 (15FEB2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 11:58:09
Query 'Per DM CLR: Per Safety Follow Up Diary Day 180 (15FEB2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'Subject has no other AEs to report.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 17:00:45
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 180 (15FEB2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 10:00:28
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:46:01
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:48:11

US3372209

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Jan 2021 20:21:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 13:35:55
User entered		
'USA-US056-2020-mRNA-1273-P301000011'	System	21 Dec 2020 13:35:51
User entered 'New'	(b) (4), (b) (6)	21 Dec 2020 13:35:51

US3372209

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Jan 2021 20:21:54
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4)	18 Dec 2020 19:51:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Dec 2020 19:51:49
	(b) (4)	
Data point term sent to Coder	System	18 Dec 2020 19:51:09
User entered 'Atrial Fibrillation'	Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

US3372209

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:47:45
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

US3372209

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:47:49
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

US3372209

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:22:15
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

US3372209

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:22:02
User entered '16 Dec 2020'	Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:47:51
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:22:07
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:22:08
User entered '17 Dec 2020'	Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:47:54
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 19:51:04

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:49:22
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Grade 4 (Grade 4)'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:22:11
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:49:30
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

US3372209

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:49:32
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:15:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:49:34
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'I'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:22:26
User entered '16 Dec 2020'	Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:22:28
User entered '17 Dec 2020'	Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:50:37
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:50:39
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:50:41
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:50:43
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:50:45
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:50:47
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible. Per protocol, causality assessment is to be stated as Related or Not related.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:47:28
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible. Per protocol, causality assessment is to be stated as Related or Not related.' answered with 'updated' (Site from Safety).	Mary Sergalis (b) (4)	23 Jan 2021 15:48:30
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	23 Jan 2021 15:48:19
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible. Per protocol, causality assessment is to be stated as Related or Not related.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 15:37:10
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:50:49
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible. Per protocol, causality assessment is to be stated as Related or Not related.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:47:33
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible. Per protocol, causality assessment is to be stated as Related or Not related.' answered with 'updated' (Site from Safety).	Mary Sergalis (b) (4)	23 Jan 2021 15:48:37
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	23 Jan 2021 15:48:19
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible. Per protocol, causality assessment is to be stated as Related or Not related.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 15:37:25
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:50:51
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	18 Dec 2020 19:51:04
	Mary Sergalis (b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:50:54
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:50:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'I'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:50:58
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:22:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:51:00
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:53:11
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:47:45
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:47:41
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:47:37
User closed query 'Per DM CLR: SAE Narrative = SUBJECT HAD AN ECHOCARDIOGRAM, CAT HEAD, ECG COMPLETED WHILE IN THE HOSPITAL. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:12:07
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Discharge summary not obtained' (Site from Safety).	Mary Sergalis (b) (4)	23 Jan 2021 16:15:11
Query 'Per DM CLR: SAE Narrative = SUBJECT HAD AN ECHOCARDIOGRAM, CAT HEAD, ECG COMPLETED WHILE IN THE HOSPITAL. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'added' (Site from DM).	Mary Sergalis (b) (4)	23 Jan 2021 16:13:56

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Generated On: 09 Jun 2021 17:15:59

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'added' (Site from Safety).	Mary Sergalis (b) (4)	23 Jan 2021 16:13:46
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no abnormalities' (Site from Safety).	Mary Sergalis (b) (4)	23 Jan 2021 15:49:13
User opened query 'Per DM CLR: SAE Narrative = SUBJECT HAD AN ECHOCARDIOGRAM, CAT HEAD, ECG COMPLETED WHILE IN THE HOSPITAL. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.'	(b) (4), (b) (6)	11 Jan 2021 06:35:22
' (Site from DM).		
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.'	(b) (4), (b) (6)	23 Dec 2020 15:04:27
(Site from Safety).		
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).'	(b) (4), (b) (6)	23 Dec 2020 15:03:57
(Site from Safety).		
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.'	(b) (4), (b) (6)	23 Dec 2020 15:03:46
(Site from Safety).		

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject was admitted to the hospital on 16-DEC-2020 for dehydration and Atrial Fibrillation after playing several games of tennis. Subject had an Echocardiogram, CAT head, ECG completed while in the hospital. Results unknown, but per subject all test were normal. Subject was discharged to home on 17-DEC-2020 with symptoms resolved and was placed on Eliquis 5 mg BID. Medical records requested.'	Mary Sergalis (b) (4)	18 Dec 2020 19:51:04

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Dec 2020 19:51:04

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Folder: Adverse Events

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Dec 2020 19:51:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Dec 2020 19:51:04

US3372209

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Total fluid volume decreased, PT: Dehydration, LLT: Dehydration - version MedDRA\\23.0.	Coder Import (b) (4)	18 Dec 2020 19:52:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Dec 2020 19:52:49
Data point term sent to Coder	System	18 Dec 2020 19:52:11
User entered 'Dehydration'	Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:15:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '16 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User entered empty.	System	18 Dec 2020 19:52:07

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '17 Dec 2020'	(b) (4)	18 Dec 2020 19:52:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User entered empty.	System	18 Dec 2020 19:52:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4)	18 Dec 2020 19:52:07
	Mary Sergalis (b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

US3372209

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

US3372209

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User closed query ' Per CDM: Per CCGs p. 33, Relationship to investigational product is expected to be "Not Applicable" only when if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 07:12:34
Query ' Per CDM: Per CCGs p. 33, Relationship to investigational product is expected to be "Not Applicable" only when if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' answered with 'updated' (Site from DM).	Mary Sergalis (b) (4)	23 Jan 2021 16:15:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	23 Jan 2021 16:15:35
User opened query ' Per CDM: Per CCGs p. 33, Relationship to investigational product is expected to be "Not Applicable" only when if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 03:25:01
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	18 Dec 2020 19:52:07
	Mary Sergalis (b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Feb 2021 16:17:12
User entered '1'	Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Feb 2021 16:17:12
User entered '0'	Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

US3372209

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

US3372209

Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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Folder: Adverse Events

Form: Adverse Events (2)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Subject took Sodium Chloride 0.9% for this AE' reason for change: Data Entry Error	(b) (4)	20 Feb 2021 16:17:12
User entered empty.	(b) (4), (b) (6)	20 Feb 2021 16:17:12
	Mary Sergalis (b) (4)	18 Dec 2020 19:52:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User entered '0'	System	18 Dec 2020 19:52:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18
User entered '1'	System	18 Dec 2020 19:52:07

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4)	23 Jan 2021 16:12:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Jan 2021 16:12:05
Data point term sent to Coder	System	23 Jan 2021 16:11:51
User entered 'Syncopy'	Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '16 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User entered empty.	System	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '16 Dec 2020'	(b) (4)	23 Jan 2021 16:11:19
	Mary Sergalis (b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4)	23 Jan 2021 16:11:19
	Mary Sergalis (b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User entered empty.	System	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4)	23 Jan 2021 16:11:19
	Mary Sergalis (b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Not Related (NOT RELATED)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Not Related (NOT RELATED)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User closed query ' Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 06:16:28
Query ' Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 16:18:05
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Feb 2021 16:17:57
User opened query ' Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 15:56:47
User entered 'None (NONE)'	Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:22:35
Signature has been broken.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:50:41
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 21:50:41
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:22:35
User closed query 'Per DM CLR-RQ: Other Action Taken = Con Procedure, However, there is no therapeutic procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Treatment Required field.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 10:02:18
' (Site from DM).		
Query 'Per DM CLR-RQ: Other Action Taken = Con Procedure, However, there is no therapeutic procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Treatment Required field.	(b) (4), (b) (6)	04 Mar 2021 21:50:52
' answered with 'Data updated.' (Site from DM).		
Signature has been broken.	(b) (4), (b) (6)	04 Mar 2021 21:50:41
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 21:50:41
User opened query 'Per DM CLR-RQ: Other Action Taken = Con Procedure, However, there is no therapeutic procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Treatment Required field.	(b) (4), (b) (6)	03 Mar 2021 03:40:15
' (Site from DM).		
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 06:56:49
' (Site from DM).		

US3372209

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 16:19:28
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 06:27:12
User entered 'I'	Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

US3372209

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

US3372209

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

US3372209

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:11:19

US3372209

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User entered '0'	System	23 Jan 2021 16:11:19

US3372209

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56
User entered '1'	System	23 Jan 2021 16:11:19

US3372209

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:15:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:56

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac disorders, signs and symptoms NEC, HLT: Cardiac signs and symptoms NEC, PT: Palpitations, LLT: Palpitation - version MedDRA\\23.0.	Coder Import (b) (4)	24 Jan 2021 18:44:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Jan 2021 18:44:53
Data point term sent to Coder	System	23 Jan 2021 16:13:52
User entered 'Palpitations'	Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '16 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User entered empty.	System	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '16 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User entered empty.	System	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Not Related (NOT RELATED)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Not Related (NOT RELATED)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User closed query ' Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 06:16:46
Query ' Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 16:19:55
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Feb 2021 16:19:48
User opened query ' Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 15:56:37
User entered 'None (NONE)'	Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:22:35
Signature has been broken.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 21:51:46
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 21:51:46
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered '0'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:22:35
User closed query 'Per DM CLR-RQ: Other Action Taken = Con Procedure, However, there is no therapeutic procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Treatment Required field. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 10:02:48
Query 'Per DM CLR-RQ: Other Action Taken = Con Procedure, However, there is no therapeutic procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Treatment Required field. ' answered with 'Data updated.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 21:51:58
Signature has been broken.	(b) (4), (b) (6)	04 Mar 2021 21:51:46
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 21:51:46
User opened query 'Per DM CLR-RQ: Other Action Taken = Con Procedure, However, there is no therapeutic procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Treatment Required field. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 03:40:33
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 06:57:04

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 16:20:02
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 06:27:24
User entered 'I'	Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User signature succeeded.	Mira Baron (b) (4)	23 Feb 2021 21:53:11
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User entered '0'	System	23 Jan 2021 16:13:17

US3372209

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05
User entered 'I'	System	23 Jan 2021 16:13:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:15:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:05

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:15:59

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:15
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:45:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:23:53
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:47:30

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:15:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Oct 2020 15:55:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:55:31
Data point term sent to Coder	System	23 Oct 2020 15:54:52
User entered 'atenolol'	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:54:34

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:15:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	23 Oct 2020 15:54:34
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'hypertension'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 15:54:34

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:15:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered '50'	Peter Jacob (b) (4)	23 Oct 2020 15:54:34
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:15:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	23 Oct 2020 15:54:34
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:15:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 15:54:34
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:15:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'once daily (QD)'	Peter Jacob (b) (4)	23 Oct 2020 15:54:34
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:15:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 15:54:34
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:15:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 15:54:34
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:15:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 15:54:34
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:15:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'un UNK 2000'	Peter Jacob (b) (4)	23 Oct 2020 15:54:34
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:15:59

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	23 Oct 2020 15:54:34
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	23 Oct 2020 15:54:34
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 15:54:34
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:15:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 15:54:34

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:15:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:54:34

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:54:34

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 15:54:34

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:15:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Oct 2020 16:53:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 16:53:39
Data point term sent to Coder	System	23 Oct 2020 16:52:30
User entered 'atorvastatin'	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 16:51:44

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:15:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'No (N)'	Peter Jacob (b) (4)	23 Oct 2020 16:51:44
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'hypercholesterolemia'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 16:51:44

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:15:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '20'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 16:51:44

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:15:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	23 Oct 2020 16:51:44
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:15:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 16:51:44
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:15:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 16:51:44
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:15:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 16:51:44
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:15:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 16:51:44

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:15:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 16:51:44
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'un UNK 2005'	Peter Jacob (b) (4)	23 Oct 2020 16:51:44
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 16:51:44

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 16:51:44

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 16:51:44
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:15:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 16:51:44

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:15:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:51:44

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:51:44

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 16:51:44

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:15:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Oct 2020 16:54:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 16:54:42
Data point term sent to Coder	System	23 Oct 2020 16:53:30
User entered 'multi-vitamins'	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 16:52:48

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:15:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:39:01
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data correct as is' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:52:57
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:29:08
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 16:52:48

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 16:52:48

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:15:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '1'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 16:52:48

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:15:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'tablet (TABLET)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 16:52:48

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:15:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 16:52:48
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:15:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 16:52:48
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:15:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 16:52:48
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:15:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 16:52:48

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:15:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 16:52:48
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'un UNK 1995'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 16:52:48
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 16:52:48

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 16:52:48

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 16:52:48
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:15:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 16:52:48

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:15:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:52:48

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:52:48

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 16:52:48

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:15:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Oct 2020 17:00:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 17:00:33
Data point term sent to Coder	System	23 Oct 2020 16:59:41
User entered 'vitamin C'	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 16:58:52

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:15:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:38:02
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data correct as is' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:53:18
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:30:11
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 16:58:52

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 16:58:52

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:15:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '500'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 16:58:52

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:15:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'mg (mg)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 16:58:52

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:15:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 16:58:52
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:15:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 16:58:52

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:15:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 16:58:52
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:15:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 16:58:52

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:15:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 16:58:52
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'un UNK 1995'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 16:58:52

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 16:58:52

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 16:58:52

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 16:58:52
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:15:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 16:58:52

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:15:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:58:52

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:58:52

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 16:58:52

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:15:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 17:10:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 17:10:40
Data point term sent to Coder	System	23 Oct 2020 17:09:54
User entered 'vitamin B12'	Peter Jacob (b) (4)	23 Oct 2020 17:09:49

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:15:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:38:14
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data correct as is' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:53:31
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:29:46
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:09:49

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:09:49

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:15:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '100'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:09:49

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:15:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	23 Oct 2020 17:09:49
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:15:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:09:49
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:15:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:09:49
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:15:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:09:49
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:15:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:09:49

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:15:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:09:49
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:15:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'un UNK 1995'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:09:49
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:09:49

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:09:49

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:09:49
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:15:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:09:49

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:15:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:09:49

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:09:49

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 17:09:49

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:15:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Oct 2020 17:20:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 17:20:29
Data point term sent to Coder	System	23 Oct 2020 17:20:03
User entered 'fish oil'	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:19:38

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:15:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:37:28
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data correct as is' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:53:48
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:28:11
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:19:38

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'dietary supplement'	Peter Jacob (b) (4)	23 Oct 2020 17:19:38
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:15:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered '1000'	Peter Jacob (b) (4)	23 Oct 2020 17:19:38
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:15:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	23 Oct 2020 17:19:38
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:15:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:19:38
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:15:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:19:38
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:15:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:19:38
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:15:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:19:38
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:15:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:19:38
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:15:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'un UNK 1995'	Peter Jacob (b) (4)	23 Oct 2020 17:19:38
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:15:59

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered '0'	Peter Jacob (b) (4)	23 Oct 2020 17:19:38
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	23 Oct 2020 17:19:38
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:19:38
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:15:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:19:38

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:15:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:19:38

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:19:38

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 17:19:38

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:15:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COQ10 [UBIDECARENONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 17:28:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 17:28:33
Data point term sent to Coder	System	23 Oct 2020 17:27:13
User entered 'coq10'	Peter Jacob (b) (4)	23 Oct 2020 17:26:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:15:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:37:45
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data correct as is' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:54:02
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:27:57
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:26:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'dietary supplement'	Peter Jacob (b) (4)	23 Oct 2020 17:26:27
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:15:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered '100'	Peter Jacob (b) (4)	23 Oct 2020 17:26:27
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:15:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	23 Oct 2020 17:26:27
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:15:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:26:27
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:15:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'once daily (QD)'	Peter Jacob (b) (4)	23 Oct 2020 17:26:27
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:15:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:26:27
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:15:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:26:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:15:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:26:27
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'un UNK 1995'	Peter Jacob (b) (4)	23 Oct 2020 17:26:27
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:26:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	23 Oct 2020 17:26:27
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:26:27
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:15:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:26:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:15:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:26:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:26:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 17:26:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:15:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 17:28:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 17:28:34
Data point term sent to Coder	System	23 Oct 2020 17:27:13
User entered 'aspirin'	Peter Jacob (b) (4)	23 Oct 2020 17:26:57

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:15:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:26:57

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'cardiac prophylaxis'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:26:57

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:15:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '81'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:26:57

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:15:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	23 Oct 2020 17:26:57
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:15:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:26:57
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:15:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:26:57

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:15:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:26:57
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:15:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:26:57

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:15:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:26:57
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:15:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	23 Oct 2020 17:27:37
User entered 'Un UNK 2010' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:27:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Oct 2020 17:26:57
User entered 'u Nov n201' (non-conformant).	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:26:57

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:15:59

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:26:57

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	23 Oct 2020 17:26:57
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:26:57
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:15:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:26:57

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:15:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:26:57

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:26:57

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 17:26:57

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Oct 2020 17:34:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 17:34:32
Data point term sent to Coder	System	23 Oct 2020 17:33:22
User entered 'magnesium'	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:33:22

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:38:33
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data correct as is' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:55:24
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:28:27
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:33:22

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:33:22

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '400'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:33:22
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	23 Oct 2020 17:33:22
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:33:22
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:33:22

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:33:22
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:33:22

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:33:22
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'un UNK 2015'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:33:22

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:33:22

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'Yes (Y)'	Peter Jacob (b) (4)	23 Oct 2020 17:33:22
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:33:22
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:33:22
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:33:22

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:33:22

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 17:33:22

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Oct 2020 17:35:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 17:35:35
Data point term sent to Coder	System	23 Oct 2020 17:34:23
User entered 'melatonin'	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:33:55

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:38:55
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data correct as is' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:55:42
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:28:50
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:33:55

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'dietary supplement'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:33:55

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '5'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:33:55

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'mg (mg)'	Peter Jacob (b) (4)	23 Oct 2020 17:33:55
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:33:55
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'once daily (QD)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:33:55

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:33:55
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Oral (ORAL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:33:55

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:33:55
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'un UNK 2015'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:33:55

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:33:55

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:33:55

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Peter Jacob (b) (4)	23 Oct 2020 17:33:55
	(b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:33:55

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:33:55

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:33:55

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 17:33:55

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:53
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 17:44:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 17:44:35
Data point term sent to Coder	System	23 Oct 2020 17:43:54
User entered 'influenza vaccine'	Peter Jacob (b) (4)	23 Oct 2020 17:43:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:53
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:43:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:53
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'influenza prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:43:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:53
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '0.5'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:43:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:53
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:43:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:53
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:43:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:53
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:43:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:53
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:43:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:53
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:43:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:53
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:43:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:53
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'un Nov 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:43:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:53
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:43:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:53
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:43:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:53
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'un Nov 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:43:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:53
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:43:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:53
User entered empty.	System	23 Oct 2020 17:43:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:53
User entered empty.	System	23 Oct 2020 17:43:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:53
User entered empty.	System	23 Oct 2020 17:43:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:56
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Oct 2020 17:47:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 17:47:41
Data point term sent to Coder	System	23 Oct 2020 17:46:02
User entered 'pneumonia vaccine'	Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:11

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:56
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:39:17
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 18:56:15
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 18:56:07
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:29:24
User entered 'No (N)'	Peter Jacob (b) (4)	23 Oct 2020 17:45:11

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:56
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'pneumonia prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:11

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:56
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '0.5'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:11

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:56
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:11

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:56
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:11

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:56
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:11

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:56
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:11

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:56
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:45:11

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:56
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:11

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:56
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:11

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:56
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:11

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:56
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:11

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:56
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'un UNK 2018'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:11

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:56
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:11

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:56
User entered empty.	System	23 Oct 2020 17:45:11

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:56
User entered empty.	System	23 Oct 2020 17:45:11

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:16:56
User entered empty.	System	23 Oct 2020 17:45:11

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:00
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 17:47:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 17:47:40
Data point term sent to Coder	System	23 Oct 2020 17:46:05
User entered 'influenza vaccine'	Peter Jacob (b) (4)	23 Oct 2020 17:45:56

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:00
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:45:56

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:00
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'influenza prophylaxis/prevention'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:56

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:00
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '0.5'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:56

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:00
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'mL (mL)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:56

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:00
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:56

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:00
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'once (ONCE)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:56

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:00
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:56

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:00
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 17:45:56

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:00
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:56

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:00
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '08 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:56

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:00
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:56

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:00
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:56

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:00
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '08 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:56

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:00
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	23 Oct 2020 17:45:56

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:00
User entered empty.	System	23 Oct 2020 17:45:56

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:00
User entered empty.	System	23 Oct 2020 17:45:56

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:00
User entered empty.	System	23 Oct 2020 17:45:56

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Jan 2021 20:24:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 19:54:15
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 19:54:15
	(b) (4)	
Data point term sent to Coder	System	18 Dec 2020 19:53:12
User entered 'Eliquis'	Mary Sergalis (b) (4)	18 Dec 2020 19:53:09

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Dec 2020 19:53:09

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Jan 2021 20:24:20
User entered 'Atrial Fibrillation'	Mary Sergalis (b) (4)	18 Dec 2020 19:53:09

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Jan 2021 20:24:21
User entered '5'	Mary Sergalis (b) (4)	18 Dec 2020 19:53:09

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 20:24:23
User entered 'mg (mg)'	Mary Sergalis (b) (4)	18 Dec 2020 19:53:09

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	18 Dec 2020 19:53:09

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Jan 2021 20:24:41
User entered 'twice daily (BID)'	Mary Sergalis (b) (4)	18 Dec 2020 19:53:09

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	18 Dec 2020 19:53:09

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Jan 2021 20:24:47
User entered 'Oral (ORAL)'	Mary Sergalis (b) (4)	18 Dec 2020 19:53:09

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	18 Dec 2020 19:53:09

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Jan 2021 20:24:55
User entered '16 Dec 2020'	Mary Sergalis (b) (4)	18 Dec 2020 19:53:09

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:59

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered '0'	Mary Sergalis (b) (4)	18 Dec 2020 19:53:09

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	18 Dec 2020 19:53:09

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	18 Dec 2020 19:53:09

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
	(b) (4)	
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Dec 2020 19:53:09

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Dec 2020 19:53:09

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Dec 2020 19:53:09

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Dec 2020 19:53:09

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Jan 2021 20:25:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	24 Jan 2021 20:25:53
Data point term sent to Coder	System	23 Jan 2021 15:53:48
User entered 'Diltiazem'	Mary Sergalis (b) (4)	23 Jan 2021 15:53:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 15:53:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Atrial Fibrillation'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 15:53:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '100'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 15:53:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'mg (mg)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 15:53:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 15:53:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'once (ONCE)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 15:53:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 15:53:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 15:53:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 15:53:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '16 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 15:53:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '0'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 15:53:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 15:53:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '16 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 15:53:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 15:53:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:05
User entered empty.	System	23 Jan 2021 15:53:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:05
User entered empty.	System	23 Jan 2021 15:53:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:17:05
User entered empty.	System	23 Jan 2021 15:53:27

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:16:51
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 Apr 2021 16:16:51
User closed query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.	(b) (4), (b) (6)	22 Feb 2021 07:13:21
' (Site from DM).		
Query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.	(b) (4), (b) (6)	20 Feb 2021 16:20:29
' answered with 'data updated' (Site from DM).		
User opened query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.	(b) (4), (b) (6)	20 Feb 2021 15:23:12
' (Site from DM).		
User signature succeeded.	Mira Baron (b) (4) (b) (4)	19 Feb 2021 22:29:32

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Jan 2021 16:02:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Jan 2021 16:02:00
Data point term sent to Coder	System	23 Jan 2021 16:00:50
User entered 'Sodium chloride 0.9%'	Mary Sergalis (b) (4)	23 Jan 2021 16:00:33

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:00:33

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Dehydration'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:00:33

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '500' reason for change: Data Entry Error	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:02:32
User entered '1000'	Mary Sergalis (b) (4)	23 Jan 2021 16:00:33

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'mL (mL)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:00:33

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered empty.	(b) (4)	23 Jan 2021 16:00:33
	Mary Sergalis (b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	23 Jan 2021 16:02:32
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	23 Jan 2021 16:02:32
User entered 'once (ONCE)'	System	23 Jan 2021 16:00:33
	Mary Sergalis (b) (4)	23 Jan 2021 16:00:33

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered empty.	(b) (4)	23 Jan 2021 16:00:33
	Mary Sergalis (b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:00:33

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered empty.	(b) (4)	23 Jan 2021 16:00:33
	Mary Sergalis (b) (4)	

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '16 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:00:33

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered '0'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:00:33

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:00:33

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
User signature succeeded.	Mira Baron (b) (4) (b) (4)	19 Feb 2021 22:29:32
User entered '16 Dec 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	23 Jan 2021 16:02:32
User entered '17 Dec 2020'	Mary Sergalis (b) (4)	23 Jan 2021 16:00:33

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:29:32
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:00:33

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
User entered empty.	System	23 Jan 2021 16:00:33

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
User entered empty.	System	23 Jan 2021 16:00:33

US3372209

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:57:05
User entered empty.	System	23 Jan 2021 16:00:33

US3372209

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:15:59

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:15
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:03:46
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	23 Oct 2020 15:47:37

US3372209

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:15:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:51
	(b) (4)	
User entered '16 Dec 2020'	Mary Sergalis (b) (4)	23 Jan 2021 16:06:01

US3372209

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:15:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:51
	(b) (4)	
User entered 'CAT Scan Brain'	Mary Sergalis (b) (4)	23 Jan 2021 16:06:01

US3372209

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:51
User entered 'Adverse Event (AE)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:06:01

US3372209

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:15:59

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:51
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	23 Jan 2021 16:06:01

US3372209

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:15:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:51
User entered '16 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:06:50

US3372209

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:15:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:51
User entered 'Chest X-Ray'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:06:50

US3372209

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:51
User entered 'Adverse Event (AE)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:06:50

US3372209

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:15:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:41
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:51
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:06:50

US3372209

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:15:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:51
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:51
User entered '16 Dec 2020'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:09:07

US3372209

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:15:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:51
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:51
User entered 'Electrocardiogram'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:09:07

US3372209

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:15:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:51
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:51
User entered 'Adverse Event (AE)'	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:09:07

US3372209

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:15:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:00:51
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:51
User entered empty.	(b) (4) Mary Sergalis (b) (4)	23 Jan 2021 16:09:07

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'USA-US056-2020-MRNA-1273-P301000011'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'Yes (Y)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'No (N)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'No (N)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'Yes (Y)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'No (N)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'No (N)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'No (N)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'Mira'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'Baron'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered '2277 Palm beach Lakes Blvd'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'West Palm Beach'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered '33409'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:49:57
User entered 'US'	System	21 Dec 2020 13:36:16

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
User entered '2'	(b) (4)	25 Jan 2021 19:49:49
User entered '1'	System	21 Dec 2020 13:36:16

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'USA-US056-2020-MRNA-1273-P301000011'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'Yes (Y)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'No (N)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'No (N)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'Yes (Y)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'No (N)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'No (N)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'No (N)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'Mira'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'Baron'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered '2277 Palm beach Lakes Blvd'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'West Palm Beach'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered '33409'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:49:57
User entered 'US'	System	21 Dec 2020 13:36:16

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
User entered '2'	(b) (4)	25 Jan 2021 19:49:49
User entered '1'	System	21 Dec 2020 13:36:16

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:15:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
User entered '21/Dec/2020 13:36'	(b) (4) System	21 Dec 2020 13:36:16

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:15:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:49:57
User entered 'I'	(b) (4), (b) (6)	21 Dec 2020 13:36:16

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'USA-US056-2020-MRNA-1273-P301000011'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'Yes (Y)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'No (N)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'No (N)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'Yes (Y)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'No (N)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'No (N)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'No (N)'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'Mira'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'Baron'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered '2277 Palm beach Lakes Blvd'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered 'West Palm Beach'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:36:11
User entered '33409'	System	21 Dec 2020 13:35:51

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:49:57
User entered 'US'	System	21 Dec 2020 13:36:16

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
User entered '2'	(b) (4)	25 Jan 2021 19:49:49
User entered '1'	System	21 Dec 2020 13:36:16

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:15:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
User entered '25/Jan/2021 14:49'	(b) (4) System	25 Jan 2021 19:49:49

US3372209

Folder: SAE USA-US056-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:15:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:11
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:49:57
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 19:49:49