

US3392049 (Prod: Benchmark Research - Metairie - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:22:36

All time stamps listed in this document are displayed in GMT

US3392049

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 22:14:44

Generated On: 09 Jun 2021 17:22:36

Participant ID

US3392049

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

US3392049

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:08:35

Generated On: 09 Jun 2021 17:22:36

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 19 AUG 2020

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID SCRN

US3392049

Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 03:08:34

Generated On: 09 Jun 2021 17:22:36

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	71
Age Units	YEARS
Age (Derived)	71
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

US3392049

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 03:08:34

Generated On: 09 Jun 2021 17:22:36

Date of Informed Consent (*dd MMM yyyy*) 19 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3392049

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 03:08:34

Generated On: 09 Jun 2021 17:22:36

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 20 Feb 2021 03:08:35

Generated On: 09 Jun 2021 17:22:36

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Apr 2021 20:02:41

Generated On: 09 Jun 2021 17:22:36

Condition	ENLARGED PROSTATE
Start date (dd MMM yyyy)	UN MAY 2015
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)	MAY 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3392049

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Apr 2021 20:02:41

Generated On: 09 Jun 2021 17:22:36

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN MAY 1997
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)	MAY 1997
Start Year (derived)	1997
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3392049

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Apr 2021 20:02:41

Generated On: 09 Jun 2021 17:22:36

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN MAY 1997
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)	MAY 1997
Start Year (derived)	1997
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3392049

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Apr 2021 20:02:41

Generated On: 09 Jun 2021 17:22:36

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN JUN 2018
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)	JUN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3392049

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 29 Apr 2021 20:02:41

Generated On: 09 Jun 2021 17:22:36

Condition	GOUT, UNSPECIFIED
Start date (dd MMM yyyy)	UN JUN 2004
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)	JUN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3392049

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Apr 2021 20:02:41

Generated On: 09 Jun 2021 17:22:36

Condition	BYPASS SURGERY
Start date (dd MMM yyyy)	UN MAY 1997
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 MAY 1997
Stop date completely unknown	False
Start Month and Year (derived)	MAY 1997
Start Year (derived)	1997
Stop Month and Year (derived)	MAY 1997
Stop Year (derived)	1997

US3392049

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 29 Apr 2021 20:02:41

Generated On: 09 Jun 2021 17:22:36

Condition	STENT PLACEMENT
Start date (dd MMM yyyy)	UN MAY 2007
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 MAY 2007
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2007
Start Year (derived)	2007
Stop Month and Year (derived)	MAY 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 29 Apr 2021 20:02:41

Generated On: 09 Jun 2021 17:22:36

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN APR 2020
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 APR 2020
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	APR 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 29 Apr 2021 20:02:41

Generated On: 09 Jun 2021 17:22:36

Condition	GALL STONES
Start date (dd MMM yyyy)	UN APR 2020
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 APR 2020
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	APR 2020
Stop Year (derived)	2020

US3392049

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 29 Apr 2021 20:02:41

Generated On: 09 Jun 2021 17:22:36

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN MAY 1997
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)	MAY 1997
Start Year (derived)	1997
Stop Month and Year (derived)	
Stop Year (derived)	

US3392049

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 29 Apr 2021 20:02:41

Generated On: 09 Jun 2021 17:22:36

Condition	OSTEO ARTHRITIS OF LEFT FOOT
Start date (dd MMM yyyy)	UN MAY 2018
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)	MAY 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 29 Apr 2021 20:02:41

Generated On: 09 Jun 2021 17:22:36

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN MAR 2018
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)	MAR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3392049

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 03:08:35

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) 19 AUG 2020

Time of assessment (*00:00-23:59*) 09:40 (24 HR)

Vital Signs Date and Time (derived) 19 AUG 2020 09:40

Height (*xxx.x*) 68.0 in

Weight (*xxx.x*) 183.0 lb

BMI (*xxx.x*) 27.88323 kg/m²

BMI units KG/M2

Temperature (*xxx.x*) ND - Not Done

Route of measurement Oral
Axillary
Other

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) 20 Feb 2021 03:08:35

Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

19 AUG 2020

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

US3392049

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 03:08:35

Generated On: 09 Jun 2021 17:22:36

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes No

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 03:08:35

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

US3392049

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 02:47:21

Generated On: 09 Jun 2021 17:22:36

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 19 AUG 2020

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID VISIT1

US3392049

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 02:47:20

Generated On: 09 Jun 2021 17:22:36

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 186996

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) 20 Feb 2021 02:47:21

Generated On: 09 Jun 2021 17:22:36

Height	ND - Not Done
Weight	ND - Not Done

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 02:47:21

Generated On: 09 Jun 2021 17:22:36

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 (<i>dd MMM yyyy</i>)	19 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:40 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 09:40
Temperature (<i>xxx.x</i>)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 02:47:21

Generated On: 09 Jun 2021 17:22:36

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 (<i>dd MMM yyyy</i>)	19 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:33 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 11:33
Temperature (<i>xxx.x</i>)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3392049

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 02:47:20

Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?

Yes

No

Date of examination (*dd MMM yyyy*)

19 AUG 2020

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

US3392049

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 02:47:20

Generated On: 09 Jun 2021 17:22:36

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) 19 AUG 2020

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

Treatment Date and Time (derived) 19 AUG 2020 11:00

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

US3392049

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 02:47:20

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	19 AUG 2020
Collection time (<i>00:00-23:59</i>)	10:30 (24 HR)
Collection date and time (derived)	19 AUG 2020 10:30

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 02:47:20

Generated On: 09 Jun 2021 17:22:36

Collection date (<i>dd MMM yyyy</i>)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:25	19 AUG 2020 10:25
Nasopharyngeal Swab 2	No		

US3392049

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:47:20

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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 97.3 °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 19 AUG 2020 11:28

PC Open Date & Time 19 AUG 2020 11:20

PC Close Date & Time 19 AUG 2020 13:50

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 19 AUG 2020 14:45

PC Close Date & Time 20 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

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

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

PC Time Stamp	20 AUG 2020 14:00
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	21 AUG 2020 20:30
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	22 AUG 2020 15:23
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 AUG 2020 16:31
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	24 AUG 2020 13:05
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	25 AUG 2020 12:00
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

19 AUG 2020 11:29

PC Open Date & Time

19 AUG 2020 11:20

PC Close Date & Time

19 AUG 2020 13:50

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

19 AUG 2020 14:45

PC Close Date & Time

20 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 2

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

20 AUG 2020 14:01

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 3

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 20:31

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

22 AUG 2020 15:24

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 5

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 AUG 2020 16:31

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 6

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

24 AUG 2020 13:05

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 7

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

25 AUG 2020 12:01

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

No

Yes

PC Time stamp	19 AUG 2020 11:30
PC Open Date & Time	19 AUG 2020 11:20
PC Close Date & Time	19 AUG 2020 13:50

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

No

Yes

PC Time stamp

PC Open Date & Time

19 AUG 2020 14:45

PC Close Date & Time

20 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

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	Yes <input type="checkbox"/>
PC Time stamp	20 AUG 2020 14:01
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

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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

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

Yes

PC Time stamp	21 AUG 2020 20:31
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

	Yes <input type="checkbox"/>
PC Time stamp	22 AUG 2020 15:24
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

	Yes <input type="checkbox"/>
PC Time stamp	23 AUG 2020 16:32
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

	Yes <input type="checkbox"/>
PC Time stamp	24 AUG 2020 13:06
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

	Yes <input type="checkbox"/>
PC Time stamp	25 AUG 2020 12:01
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3392049

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:01:38

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 26 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3392049

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:01:38

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3392049

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 02:28:15

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3392049

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:28:15

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3392049

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 02:08:50

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 9 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3392049

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:08:50

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3392049

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 04:36:32

Generated On: 09 Jun 2021 17:22:36

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 14 SEP 2020

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID VISIT2

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 04:36:32

Generated On: 09 Jun 2021 17:22:36

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 (<i>dd MMM yyyy</i>)	14 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:12 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 10:12
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	77 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 04:36:32

Generated On: 09 Jun 2021 17:22:36

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 (<i>dd MMM yyyy</i>)	14 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:44 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 11:44
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	79 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3392049

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 04:36:32

Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3392049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 04:36:32

Generated On: 09 Jun 2021 17:22:36

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) 14 SEP 2020

What was the treatment time? (00:00-23:59) 11:12 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 11:12

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

What was the frequency of the study treatment dosing? ONCE

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

US3392049

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 04:36:32

Generated On: 09 Jun 2021 17:22:36

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 14 SEP 2020

Collection time (*00:00-23:59*) 10:30 (24 HR)

Collection date and time (derived) 14 SEP 2020 10:30

US3392049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 04:36:32

Generated On: 09 Jun 2021 17:22:36

Collection date (<i>dd MMM yyyy</i>)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:27	14 SEP 2020 10:27
Nasopharyngeal Swab 2	No		

US3392049

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 04:36:32

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp 14 SEP 2020 11:49

PC Open Date & Time 14 SEP 2020 11:32

PC Close Date & Time 14 SEP 2020 14:02

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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 97.8 °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 14 SEP 2020 17:05
PC Open Date & Time 14 SEP 2020 14:57
PC Close Date & Time 15 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

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

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

PC Time Stamp	15 SEP 2020 12:00
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

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

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

PC Time Stamp	17 SEP 2020 09:49
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

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

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

PC Time Stamp	17 SEP 2020 12:01
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	19 SEP 2020 07:16
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	19 SEP 2020 12:01
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 SEP 2020 12:00
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

14 SEP 2020 11:50

PC Open Date & Time

14 SEP 2020 11:32

PC Close Date & Time

14 SEP 2020 14:02

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

14 SEP 2020 17:06

PC Open Date & Time

14 SEP 2020 14:57

PC Close Date & Time

15 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 2

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	15 SEP 2020 12:01
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 3

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

17 SEP 2020 09:49

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 4

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

17 SEP 2020 12:01

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 5

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	19 SEP 2020 07:16
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 6

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

19 SEP 2020 12:01

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 7

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

20 SEP 2020 12:01

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

No

Yes

PC Time stamp	14 SEP 2020 11:50
PC Open Date & Time	14 SEP 2020 11:32
PC Close Date & Time	14 SEP 2020 14:02

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

No

Yes

PC Time stamp	14 SEP 2020 17:06
PC Open Date & Time	14 SEP 2020 14:57
PC Close Date & Time	15 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

	Yes <input type="checkbox"/>
PC Time stamp	15 SEP 2020 12:01
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

	Yes <input type="checkbox"/>
PC Time stamp	17 SEP 2020 09:50
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

	Yes <input type="checkbox"/>
PC Time stamp	17 SEP 2020 12:02
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

	Yes <input type="checkbox"/>
PC Time stamp	19 SEP 2020 07:16
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

	Yes <input type="checkbox"/>
PC Time stamp	19 SEP 2020 12:02
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

	Yes <input type="checkbox"/>
PC Time stamp	20 SEP 2020 12:01
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3392049

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:52:24

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3392049

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:52:24

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3392049

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:35:39

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3392049

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:35:39

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3392049

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:18:25

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 5 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3392049

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:18:25

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3392049

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 05:18:48

Generated On: 09 Jun 2021 17:22:36

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 9 OCT 2020

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID VISIT3

US3392049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 05:18:48

Generated On: 09 Jun 2021 17:22:36

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) _____

US3392049

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 05:18:48

Generated On: 09 Jun 2021 17:22:36

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.

US3392049

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 05:18:48

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	9 OCT 2020
Collection time (<i>00:00-23:59</i>)	10:15 (24 HR)
Collection date and time (derived)	9 OCT 2020 10:15

US3392049

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 05:18:48

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 64

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

No

Yes

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

No

Yes

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

Date and time of submission 19 OCT 2020 07:52:46

Patient Cloud Open Date & Time 19 OCT 2020 00:01

Patient Cloud Close Date & Time 23 OCT 2020 23:59

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 71

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

No

Yes

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

No

Yes

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

Date and time of submission 26 OCT 2020 09:31:05

Patient Cloud Open Date & Time 26 OCT 2020 00:01

Patient Cloud Close Date & Time 30 OCT 2020 23:59

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 78

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

No

Yes

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

No

Yes

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

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

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

Date and time of submission

05 NOV 2020 17:56:57

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Yes

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

No

Yes

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

Date and time of submission 16 NOV 2020 08:10:10

Patient Cloud Open Date & Time 16 NOV 2020 00:01

Patient Cloud Close Date & Time 20 NOV 2020 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 07:49:48
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 04 DEC 2020 07:21:33

Patient Cloud Open Date & Time 04 DEC 2020 00:01

Patient Cloud Close Date & Time 08 DEC 2020 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 00:02:20
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	18 DEC 2020 08:00:57
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 <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	28 DEC 2020 19:10:55
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 138

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

No

Yes

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

No

Yes

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

Date and time of submission 03 JAN 2021 15:17:43

Patient Cloud Open Date & Time 01 JAN 2021 00:01

Patient Cloud Close Date & Time 05 JAN 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 12:01:38
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 <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	15 JAN 2021 08:07:21
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 JAN 2021 12:44:55
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 29 JAN 2021 08:26:08

Patient Cloud Open Date & Time 29 JAN 2021 00:01

Patient Cloud Close Date & Time 02 FEB 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 173

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

No
Yes

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

No
Yes

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

Date and time of submission	05 FEB 2021 06:56:24
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 180

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

No

Yes

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

No

Yes

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

Date and time of submission 12 FEB 2021 06:57:34

Patient Cloud Open Date & Time 12 FEB 2021 00:01

Patient Cloud Close Date & Time 16 FEB 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 11:52:57
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 FEB 2021 12:06:36
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 15:02:31
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 <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	12 MAR 2021 08:27:37
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 20 MAR 2021 09:14:30

Patient Cloud Open Date & Time 19 MAR 2021 00:01

Patient Cloud Close Date & Time 23 MAR 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	28 MAR 2021 12:00:48
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 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 APR 2021 10:10:29
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	09 APR 2021 08:14:10
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	16 APR 2021 12:00:29
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 24 APR 2021 09:08:13

Patient Cloud Open Date & Time 23 APR 2021 00:01

Patient Cloud Close Date & Time 27 APR 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 30 APR 2021 08:59:46

Patient Cloud Open Date & Time 30 APR 2021 00:01

Patient Cloud Close Date & Time 04 MAY 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 264

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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
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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 299

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2021 00:01
Patient Cloud Close Date & Time	29 JUN 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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
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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	16 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	23 JUL 2021 00:01
Patient Cloud Close Date & Time	27 JUL 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	13 AUG 2021 00:01
Patient Cloud Close Date & Time	17 AUG 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2021 00:01
Patient Cloud Close Date & Time	24 AUG 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	31 AUG 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 383

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	03 SEP 2021 00:01
Patient Cloud Close Date & Time	07 SEP 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 390

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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
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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Close Date & Time](#) 12 OCT 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 425

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	02 NOV 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2021 00:01
Patient Cloud Close Date & Time	16 NOV 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 460

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	19 NOV 2021 00:01
Patient Cloud Close Date & Time	23 NOV 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	26 NOV 2021 00:01
Patient Cloud Close Date & Time	30 NOV 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	03 DEC 2021 00:01
Patient Cloud Close Date & Time	07 DEC 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Close Date & Time](#) 28 DEC 2021 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	21 JAN 2022 00:01
Patient Cloud Close Date & Time	25 JAN 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 530

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	28 JAN 2022 00:01
Patient Cloud Close Date & Time	01 FEB 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	04 FEB 2022 00:01
Patient Cloud Close Date & Time	08 FEB 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	11 FEB 2022 00:01
Patient Cloud Close Date & Time	15 FEB 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	18 FEB 2022 00:01
Patient Cloud Close Date & Time	22 FEB 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	12 APR 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 607

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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
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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#) 24 MAY 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	14 JUN 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	01 JUL 2022 00:01
Patient Cloud Close Date & Time	05 JUL 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	05 AUG 2022 00:01
Patient Cloud Close Date & Time	09 AUG 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	12 AUG 2022 00:01
Patient Cloud Close Date & Time	16 AUG 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	19 AUG 2022 00:01
Patient Cloud Close Date & Time	23 AUG 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2022 00:01
Patient Cloud Close Date & Time	30 AUG 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 747

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 768

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#) 27 SEP 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2022 00:01
Patient Cloud Close Date & Time	04 OCT 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 18 OCT 2022 23:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this 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	21 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3392049

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:22:36

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 10:13:09

US3392049

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:52:21

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3392049

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:52:21

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3392049

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3392049

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3392049

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 11 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3392049

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3392049

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 08 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3392049

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3392049

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 1 MAR 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID VISIT4

US3392049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

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) _____

US3392049

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

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.

US3392049

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 1 MAR 2021

Collection time (*00:00-23:59*) 10:20 (24 HR)

Collection date and time (derived) 1 MAR 2021 10:20

US3392049

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3392049

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 09 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3392049

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3392049

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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 _____

US3392049

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3392049

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392049

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:22:36

Generate Next COVID-19 Assessment

Yes

No

US3392049

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 08 JAN 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID UNBLND_DECIDE

US3392049

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Date of updated informed consent (<i>dd MMM yyyy</i>)	08 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>)	08 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

US3392049

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Height	68.0 in
Weight	180.0 lb
BMI (xxx.x)	27.42613

US3392049

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Height	68.0 in
Weight	180.0 lb
BMI (xxx.x)	27.42613
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)	08 JAN 2021
Time of assessment (00:00-23:59)	10:32 (24 HR)
Vital Signs Date and Time (derived)	08 JAN 2021 10:32
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3392049

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Height	68.0 in
Weight	180.0 lb
BMI (xxx.x)	27.42613
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)	08 JAN 2021
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	08 JAN 2021 12:15
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3392049

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

08 JAN 2021

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

US3392049

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

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) 08 JAN 2021

What was the treatment time? (00:00-23:59) 11:43 (24 HR)

Treatment Date and Time (derived) 08 JAN 2021 11:43

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

US3392049

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) 08 JAN 2021

Collection time (*00:00-23:59*) 10:40 (24 HR)

Collection date and time (derived) 08 JAN 2021 10:40

US3392049

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 08 JAN 2021

Collection time (*00:00 - 23:59*) 10:42

Collection Date and Time (derived) 08 JAN 2021 10:42

US3392049

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3392049

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3392049

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:14:44

Generated On: 09 Jun 2021 17:22:36

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 2 FEB 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID OLD29

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 22:14:44

Generated On: 09 Jun 2021 17:22:36

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 (<i>dd MMM yyyy</i>)	2 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	09:45 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 09:45
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	90 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 22:14:44

Generated On: 09 Jun 2021 17:22:36

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 (<i>dd MMM yyyy</i>)	2 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	10:48 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 10:48
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	97 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3392049

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:14:44

Generated On: 09 Jun 2021 17:22:36

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.

US3392049

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 22:14:44

Generated On: 09 Jun 2021 17:22:36

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) 2 FEB 2021

What was the treatment time? (00:00-23:59) 10:09 (24 HR)

Treatment Date and Time (derived) 2 FEB 2021 10:09

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

US3392049

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:14:44

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3392049

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3392049

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3392049

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 1 MAR 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID OLD57

US3392049

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

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) _____

US3392049

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:14:45

Generated On: 09 Jun 2021 17:22:36

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.

US3392049

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:14:44

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	1 MAR 2021
Collection time (<i>00:00-23:59</i>)	10:20 (24 HR)
Collection date and time (derived)	1 MAR 2021 10:20

US3392049

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 22:05:16

Generated On: 09 Jun 2021 17:22:36

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:05:15

Generated On: 09 Jun 2021 17:22:36

AEID USA-US119-2020-MRNA-1273-P30
1000013

Adverse event ACUTE MYOCARDIAL
INFARCTION

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) 21 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) 23 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 True

Hospital Admission Date (dd MMM yyyy) 21 DEC 2020

Hospital Discharge Date (dd MMM yyyy) 23 DEC 2020

Admitted to ICU? Yes
No
Unknown

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:05:15

Generated On: 09 Jun 2021 17:22:36

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 Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT WAS ADMITTED TO HOSPITAL FOR ACUTE MYOCARDIAL INFARCTION. WILL UPDATE ONCE HOSPITAL RECORDS ARE RECEIVED.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:05:15

Generated On: 09 Jun 2021 17:22:36

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 29 Apr 2021 20:02:40

Generated On: 09 Jun 2021 17:22:36

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

Yes

No

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

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

Name of Medication ZOLPIDEM

Prophylaxis Yes
No

Indication INSOMNIA

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

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 JUN 2018

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

Name of Medication INDOMETHACIN

Prophylaxis Yes
No

Indication GOUT, UNSPECIFIED

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

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 JUN 2004

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

Name of Medication ALLOPURINOL

Prophylaxis Yes
No

Indication GOUT, UNSPECIFIED

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

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 JAN 2019

Start date completely unknown _____ False

Ongoing? _____ Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? _____ Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) _____ 802
803
804

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

Name of Medication METOPROLOL

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

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 MAY 1997

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

Name of Medication ALPRAZOLAM

Prophylaxis Yes
No

Indication INSOMNIA

Dose per administration 0.25

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

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 JUN 2018

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

Name of Medication TAMSULOSIN

Prophylaxis Yes
No

Indication ENLARGED PROSTATE

Dose per administration 0.4

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

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
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

Name of Medication CELECOXIB

Prophylaxis Yes
No

Indication ARTHRITIS, LEFT FOOT

Dose per administration 200

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

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 MAY 2018

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

Name of Medication ROSUVASTATIN

Prophylaxis Yes
No

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

	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 MAR 1997

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

Name of Medication ESOMEPRAZOLE

Prophylaxis Yes
No

Indication GASTROESOPHAGEAL REFLUX
DISEASE

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

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

	Intraocular	<input type="checkbox"/>
	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 MAR 2016

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

Name of Medication REPATHA PUSHTRONEX

Prophylaxis Yes
No

Indication HYPERCHOLESTEROLEMIA

Dose per administration 420-3.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify MG-ML

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

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 JUN 2018

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

Name of Medication POTASSIUM CITRATE

Prophylaxis Yes
No

Indication WORSENING CORONARY
ARTERY DISEASE

Dose per administration 15

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify MEQ

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

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

	Intraocular	<input type="checkbox"/>
	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 JUN 2017

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

Name of Medication FOLIC ACID

Prophylaxis Yes
No

Indication WORSENING CORONARY ARTERY DISEASE

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

Intraocular	<input type="checkbox"/>
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 MAY 1997

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

Name of Medication FISH OIL [OMEGA-3 FATTY ACIDS]

Prophylaxis Yes
No

Indication WORSENING CORONARY ARTERYDISEASE

Dose per administration 300-1000

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

	Intraocular	<input type="checkbox"/>
	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 MAY 1997

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

Name of Medication MULTIVITAMIN

Prophylaxis Yes
No

Indication WORSENING CORONARY
ARTERY DISEASE

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify TAB

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

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

Intraocular	<input type="checkbox"/>
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 MAY 1997

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication CARDIOVASCULAR DISEASE

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 20:02:39

Generated On: 09 Jun 2021 17:22:36

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 MAY 1997

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3392049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Apr 2021 20:02:40

Generated On: 09 Jun 2021 17:22:36

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3392049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Apr 2021 20:02:40

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 DEC 2020	CARDIAC CATHETERIZATION FOR NON-ST ELEVATED MYOCARDIAL INFARCTION	Adverse Event	
23 DEC 2020	ECHOCARDIOGRAM FOR NON-ST ELEVATED MYOCARDIAL INFARCTION	Adverse Event	

US3392049

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:22:36

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

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 20:02:41

Generated On: 09 Jun 2021 17:22:36

SAEID	USA-US119-2020-MRNA-1273-P30 1000013
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	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 20:02:41

Generated On: 09 Jun 2021 17:22:36

SAEID USA-US119-2020-MRNA-1273-P30
1000013

Serious Yes
No

Death Yes
No

Life threatening Yes
No

Requires inpatient or prolongation of existing Hospitalization Yes
No

Persistent or significant disability or incapacity Yes
No

Congenital anomaly or birth defect Yes
No

Other medically important event Yes
No

Investigator's First Name MICHAEL

Investigator's Last Name COTUGNO

Site Address: Street _____

Site Address: City _____

Site Address: State _____

Site Address: Postal Code _____

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 2

Date of submission (Pre-filled from custom function) 29/DEC/2020 10:18

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

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 20:02:41

Generated On: 09 Jun 2021 17:22:36

SAEID	USA-US119-2020-MRNA-1273-P30 1000013
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	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	07/JAN/2021 19:28
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

US3392049 (Prod: Benchmark Research - Metairie - PPDS)

US3392049

Form: Participant Creation

Generated On: 09 Jun 2021 17:22:36

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'US3392049'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 14:19:28

US3392049

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'Yes (Y)'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:45:08

US3392049

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 14:19:29

US3392049

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[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 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'Clinic (Clinic)'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:45:08

US3392049

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'SCRN'	System	19 Aug 2020 15:45:08

US3392049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered (b) (6) 1948'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 14:19:30

US3392049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '71'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:00

US3392049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'YEARS'	System	19 Aug 2020 15:46:00

US3392049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '71'	System	19 Aug 2020 15:46:20

US3392049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'Male (M)'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:00

US3392049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:00

US3392049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '1'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:00

US3392049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:00

US3392049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:00

US3392049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:00

US3392049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:00

US3392049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:00

US3392049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered empty.	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:00

US3392049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:00

US3392049

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:00

US3392049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '19 Aug 2020'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:20

US3392049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'Aug 2020'	System	19 Aug 2020 15:46:20

US3392049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '2020'	System	19 Aug 2020 15:46:20

US3392049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'Amendment 2 (2)'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:20

US3392049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'Yes (Y)'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:20

US3392049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered empty.	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:20

US3392049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered empty.	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:20

US3392049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'No (N)'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:20

US3392049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 14:19:29

US3392049

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '1'	System	19 Aug 2020 15:46:28

US3392049

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'Yes (Y)'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 15:46:28

US3392049

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:22:36

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:10:37

US3392049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User coded data point as SOC: Reproductive system and breast disorders, HLG: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 13:11:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 13:11:41
Data point term sent to Coder	System	28 Aug 2020 13:11:18
User entered 'enlarged prostate'	Brandon Illickal (b) (4)	28 Aug 2020 13:10:58

US3392049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'un May 2015'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:10:58

US3392049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:10:58

US3392049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:10:58

US3392049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered empty.	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:10:58

US3392049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:10:58

US3392049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'May 2015'	System	28 Aug 2020 13:10:58

US3392049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '2015'	System	28 Aug 2020 13:10:58

US3392049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	System	28 Aug 2020 13:10:58

US3392049

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	System	28 Aug 2020 13:10:58

US3392049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	28 Aug 2020 13:13:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 13:13:41
Data point term sent to Coder	System	28 Aug 2020 13:12:19
User entered 'coronary artery disease'	Brandon Illickal (b) (4)	28 Aug 2020 13:11:22

US3392049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'un May 1997'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:11:22

US3392049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:11:22

US3392049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:11:22

US3392049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered empty.	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:11:22

US3392049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:11:22

US3392049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'May 1997'	System	28 Aug 2020 13:11:22

US3392049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '1997'	System	28 Aug 2020 13:11:22

US3392049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	System	28 Aug 2020 13:11:22

US3392049

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	System	28 Aug 2020 13:11:22

US3392049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	28 Aug 2020 13:13:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 13:13:41
Data point term sent to Coder	System	28 Aug 2020 13:12:21
User entered 'hypercholesterolemia'	Brandon Illickal (b) (4)	28 Aug 2020 13:12:09

US3392049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'un May 1997'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:12:09

US3392049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:12:09

US3392049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:12:09

US3392049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered empty.	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:12:09

US3392049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:12:09

US3392049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'May 1997'	System	28 Aug 2020 13:12:09

US3392049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '1997'	System	28 Aug 2020 13:12:09

US3392049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	System	28 Aug 2020 13:12:09

US3392049

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	System	28 Aug 2020 13:12:09

US3392049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	28 Aug 2020 13:14:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 13:14:43
Data point term sent to Coder	System	28 Aug 2020 13:13:24
User entered 'insomnia'	Brandon Illickal (b) (4)	28 Aug 2020 13:13:18

US3392049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'un Jun 2018'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:13:18

US3392049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:13:18

US3392049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:13:18

US3392049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered empty.	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:13:18

US3392049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 03:08:35
User entered '0'	Brandon Illickal (b) (4) (b) (4) (b) (4)	28 Aug 2020 13:13:18

US3392049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'Jun 2018'	System	28 Aug 2020 13:13:18

US3392049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '2018'	System	28 Aug 2020 13:13:18

US3392049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	System	28 Aug 2020 13:13:18

US3392049

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	System	28 Aug 2020 13:13:18

US3392049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of GOUT (arms, Legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 13:19:57
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout, unspecified - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 16:55:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 16:55:39
Data point term sent to Coder	System	22 Oct 2020 16:54:31
Query 'Per DM CLR: Please update the condition to include the type and/or location of GOUT (arms, Legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'DATA UPDATED PER QUERY RESOLUTION ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:54:00
Coding entries removed.	(b) (4), (b) (6)	22 Oct 2020 16:53:42
User entered 'GOUT, UNSPECIFIED' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:53:42

US3392049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of GOUT (arms, Legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 09:15:28
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 13:15:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 13:15:40
Data point term sent to Coder	System	28 Aug 2020 13:14:25
User entered 'gout'	Brandon Illickal (b) (4)	28 Aug 2020 13:13:33

US3392049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'un Jun 2004'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:13:33

US3392049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:13:33

US3392049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:13:33

US3392049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered empty.	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:13:33

US3392049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 03:08:35
User entered '0'	Brandon Illickal (b) (4) (b) (4) (b) (4)	28 Aug 2020 13:13:33

US3392049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'Jun 2004'	System	28 Aug 2020 13:13:33

US3392049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '2004'	System	28 Aug 2020 13:13:33

US3392049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	System	28 Aug 2020 13:13:33

US3392049

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	System	28 Aug 2020 13:13:33

US3392049

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User coded data point as SOC: Surgical and medical procedures, HLT: Vascular therapeutic procedures, HLT: Vascular therapeutic procedures NEC, PT: Vascular graft, LLT: Bypass surgery - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	28 Aug 2020 13:16:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 13:16:43
Data point term sent to Coder	System	28 Aug 2020 13:15:26
User entered 'bypass surgery'	Brandon Illickal (b) (4)	28 Aug 2020 13:14:32

US3392049

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'un May 1997'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:14:32

US3392049

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:14:32

US3392049

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:14:32

US3392049

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'un May 1997'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:14:32

US3392049

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 03:08:35
User entered '0'	Brandon Illickal (b) (4) (b) (4) (b) (4)	28 Aug 2020 13:14:32

US3392049

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'May 1997'	System	28 Aug 2020 13:14:32

US3392049

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '1997'	System	28 Aug 2020 13:14:32

US3392049

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'May 1997'	System	28 Aug 2020 13:14:32

US3392049

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '1997'	System	28 Aug 2020 13:14:32

US3392049

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User coded data point as SOC: Surgical and medical procedures, HLG: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Stent placement, LLT: Stent placement - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	28 Aug 2020 13:16:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 13:16:43
Data point term sent to Coder	System	28 Aug 2020 13:15:26
User entered 'stent placement'	Brandon Illickal (b) (4)	28 Aug 2020 13:15:02

US3392049

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'un May 2007'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:15:02

US3392049

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:15:02

US3392049

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 03:08:35
User entered 'No (N)'	Brandon Illickal (b) (4) (b) (4) (b) (4)	28 Aug 2020 13:15:02

US3392049

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'un May 2007'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:15:02

US3392049

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 03:08:35
User entered '0'	Brandon Illickal (b) (4) [Redacted] [Redacted]	28 Aug 2020 13:15:02

US3392049

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'May 2007'	System	28 Aug 2020 13:15:02

US3392049

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '2007'	System	28 Aug 2020 13:15:02

US3392049

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'May 2007'	System	28 Aug 2020 13:15:02

US3392049

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '2007'	System	28 Aug 2020 13:15:02

US3392049

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 13:20:26
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'MEDICAL HISTORY ECRF DATA UPDATED PER SOURCE DOCUMENTATION.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 17:00:12
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 09:15:54
User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 13:16:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 13:16:44
Data point term sent to Coder	System	28 Aug 2020 13:16:26
User entered 'Cholecystectomy'	Brandon Illickal (b) (4)	28 Aug 2020 13:16:04

US3392049

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'un Apr 2020'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:16:04

US3392049

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 03:08:35
User entered '0'	Brandon Illickal (b) (4) [Redacted] [Redacted]	28 Aug 2020 13:16:04

US3392049

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 13:20:31
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'DATA UPDATED PER QUERY RESOLUTION' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 17:00:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:59:37
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 09:16:06
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	28 Aug 2020 13:16:04

US3392049

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'UN Apr 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:59:37
User entered empty.	Brandon Illickal (b) (4)	28 Aug 2020 13:16:04

US3392049

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:16:04

US3392049

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'Apr 2020'	System	28 Aug 2020 13:16:04

US3392049

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '2020'	System	28 Aug 2020 13:16:04

US3392049

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'Apr 2020'	System	22 Oct 2020 16:59:37
User entered empty.	System	28 Aug 2020 13:16:04

US3392049

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '2020'	System	22 Oct 2020 16:59:37
User entered empty.	System	28 Aug 2020 13:16:04

US3392049

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallstones - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	22 Oct 2020 16:57:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 16:57:31
Data point term sent to Coder	System	22 Oct 2020 16:56:33
User entered 'GALL STONES'	(b) (4), (b) (6)	22 Oct 2020 16:55:40

US3392049

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'UN Apr 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:55:40

US3392049

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:55:40

US3392049

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:55:40

US3392049

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'UN Apr 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:55:40

US3392049

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:55:40

US3392049

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'Apr 2020'	System	22 Oct 2020 16:55:40

US3392049

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '2020'	System	22 Oct 2020 16:55:40

US3392049

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'Apr 2020'	System	22 Oct 2020 16:55:40

US3392049

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '2020'	System	22 Oct 2020 16:55:40

US3392049

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:41:56
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) (b) (4)	25 Feb 2021 00:54:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 00:54:11
Data point term sent to Coder	System	25 Feb 2021 00:53:10
User entered 'hypertension'	Brandon Illickal (b) (4)	25 Feb 2021 00:53:00

US3392049

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'un May 1997'	Brandon Illickal (b) (4)	25 Feb 2021 00:53:00

US3392049

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '0'	Brandon Illickal (b) (4)	25 Feb 2021 00:53:00

US3392049

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	25 Feb 2021 00:53:00

US3392049

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	Brandon Illickal (b) (4)	25 Feb 2021 00:53:00

US3392049

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '0'	Brandon Illickal (b) (4)	25 Feb 2021 00:53:00

US3392049

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'May 1997'	System	25 Feb 2021 00:53:00

US3392049

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '1997'	System	25 Feb 2021 00:53:00

US3392049

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	System	25 Feb 2021 00:53:00

US3392049

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	System	25 Feb 2021 00:53:00

US3392049

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:41:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Foot osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 13:14:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 13:14:40
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:41:21
Data point term sent to Coder	System	18 Mar 2021 20:18:01
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 20:17:34
Coding entries removed.	(b) (4), (b) (6)	18 Mar 2021 20:17:25
User entered 'Osteo ARTHRITIS OF LEFT FOOT' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 20:17:25
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 13:51:16

US3392049

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 22:20:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 22:20:40
Data point term sent to Coder	System	03 Mar 2021 16:50:07
User entered 'arthritis of left foot'	(b) (4), (b) (6) (b) (4)	03 Mar 2021 16:49:41

US3392049

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'un May 2018'	(b) (4), (b) (6)	03 Mar 2021 16:49:41

US3392049

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 16:49:41

US3392049

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 16:49:41

US3392049

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 16:49:41

US3392049

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 16:49:41

US3392049

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'May 2018'	System	03 Mar 2021 16:49:41

US3392049

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '2018'	System	03 Mar 2021 16:49:41

US3392049

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	System	03 Mar 2021 16:49:41

US3392049

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	System	03 Mar 2021 16:49:41

US3392049

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:41:56
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 16:52:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 16:52:42
Data point term sent to Coder	System	03 Mar 2021 16:52:12
User entered 'Gastroesophageal Reflux Disease'	(b) (4), (b) (6)	03 Mar 2021 16:51:35

US3392049

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'un Mar 2018'	(b) (4), (b) (6)	03 Mar 2021 16:51:35

US3392049

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 16:51:35

US3392049

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Mar 2021 16:51:35

US3392049

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 16:51:35

US3392049

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
Data hard locked.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 16:51:35

US3392049

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'Mar 2018'	System	03 Mar 2021 16:51:35

US3392049

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '2018'	System	03 Mar 2021 16:51:35

US3392049

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	System	03 Mar 2021 16:51:35

US3392049

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:59:28
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:21:34
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered empty.	System	03 Mar 2021 16:51:35

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:17:00

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '19 Aug 2020'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:17:00

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '09:40'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:17:00

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '19 Aug 2020 09:40'	System	28 Aug 2020 13:17:00

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '68.0' in	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:17:00
DataPoint set to visible.	System	19 Aug 2020 15:46:28

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '183.0' lb	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:17:00
DataPoint set to visible.	System	19 Aug 2020 15:46:28

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered '27.88323'	System	28 Aug 2020 13:17:00
DataPoint set to visible.	System	19 Aug 2020 15:46:28

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'kg/m2'	System	28 Aug 2020 13:17:00
DataPoint set to visible.	System	19 Aug 2020 15:46:28

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
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)	01 Oct 2020 16:03:33
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 'updated' (Site from DM).	Brandon Illickal (b) (4)	28 Sep 2020 18:09:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	28 Sep 2020 18:09:10
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)	23 Sep 2020 17:42:16
User entered '97.4' F	Brandon Illickal (b) (4)	28 Aug 2020 13:17:00

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 03:08:35
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	28 Sep 2020 18:09:10
User entered 'Oral (Oral)'	Brandon Illickal (b) (4)	28 Aug 2020 13:17:00

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered empty.	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:17:00

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 03:08:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	28 Sep 2020 18:09:10
User entered '76'	Brandon Illickal (b) (4)	28 Aug 2020 13:17:00

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'bpm'	System	28 Aug 2020 13:17:00

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 03:08:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	28 Sep 2020 18:09:10
User entered '16'	Brandon Illickal (b) (4)	28 Aug 2020 13:17:00

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'breaths/min'	System	28 Aug 2020 13:17:00

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 03:08:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	28 Sep 2020 18:09:10
User entered '126'	Brandon Illickal (b) (4)	28 Aug 2020 13:17:00

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'mmHg'	System	28 Aug 2020 13:17:00

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 03:08:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	28 Sep 2020 18:09:10
User entered '81'	Brandon Illickal (b) (4)	28 Aug 2020 13:17:00

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User entered 'mmHg'	System	28 Aug 2020 13:17:00

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56

US3392049

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56

US3392049

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:17:11

US3392049

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 03:08:35
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		30 Sep 2020 21:00:31
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		14 Sep 2020 16:26:30
User entered '19 Aug 2020'	Brandon Illickal (b) (4) (b) (4) (b) (4)	28 Aug 2020 13:17:11

US3392049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[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 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[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 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[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 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[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 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[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 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[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 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

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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 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered empty.	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

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[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 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[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 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '1'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:41:56
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:08:35
User entered empty.	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:15

US3392049

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'Yes (Y)'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 16:01:49

US3392049

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '19 Aug 2020'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 16:01:49

US3392049

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'Clinic (Clinic)'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 16:01:49

US3392049

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'VISIT1'	System	19 Aug 2020 16:01:49

US3392049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 15:39:22

US3392049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:31:40
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:31:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 15:39:22
User entered '186996' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 15:39:22

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Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 15:39:22

US3392049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:20:46

US3392049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:20:46

US3392049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:20:46

US3392049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:20:46

US3392049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:20:46

US3392049

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 18:08:50
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:35:38
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:29:19

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User closed query '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)	01 Oct 2020 16:03:37
Query '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. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	28 Sep 2020 18:08:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	28 Sep 2020 18:08:41
User opened query '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)	23 Sep 2020 17:42:33
User entered '68.0' in	Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 02:47:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	28 Sep 2020 18:08:41
User entered '183.0' lb	Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User closed query '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)	01 Oct 2020 16:03:37
Query '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. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	28 Sep 2020 18:08:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	28 Sep 2020 18:08:41
User opened query '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)	23 Sep 2020 17:42:33
User entered '68.0' in	Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 02:47:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	28 Sep 2020 18:08:41
User entered '183.0' lb	Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User accepted default value 'Pre-Dose (PREDOSE)'	Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '19 Aug 2020'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 02:47:24
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 13:20:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		28 Aug 2020 13:20:29
User entered '09:40' reason for change: Per Query Resolution	Brandon Illickal (b) (4) (b) (4) (b) (4)	28 Aug 2020 13:20:29
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 13:18:40
User entered empty.	Brandon Illickal (b) (4) (b) (4) (b) (4)	28 Aug 2020 13:18:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered '19 Aug 2020 09:40'	System	28 Aug 2020 13:20:29
User entered empty.	System	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 02:47:24
User entered '97.4' F	Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'Oral (Oral)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered empty.	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '76'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'bpm'	System	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 02:47:24
User entered '16'	Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'breaths/min'	System	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '126'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'mmHg'	System	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '81'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'mmHg'	System	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User closed query '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)	01 Oct 2020 16:03:37
Query '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. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	28 Sep 2020 18:08:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	28 Sep 2020 18:08:41
User opened query '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)	23 Sep 2020 17:42:33
User entered '68.0' in	Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 02:47:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	28 Sep 2020 18:08:41
User entered '183.0' lb	Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User accepted default value 'Post-Dose (POSTDOSE)'	Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '19 Aug 2020'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 02:47:24
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 13:20:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		28 Aug 2020 13:20:29
User entered '11:33' reason for change: Per Query Resolution	Brandon Illickal (b) (4) [Redacted]	28 Aug 2020 13:20:29
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 13:18:40
User entered empty.	Brandon Illickal (b) (4) [Redacted]	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered '19 Aug 2020 11:33'	System	28 Aug 2020 13:20:29
User entered empty.	System	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '97.3' F	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'Oral (Oral)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered empty.	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '76'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'bpm'	System	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 02:47:24
User entered '16'	Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'breaths/min'	System	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '128'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'mmHg'	System	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '82'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'mmHg'	System	28 Aug 2020 13:18:40

US3392049

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'Yes (Y)'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 16:02:01

US3392049

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '19 Aug 2020'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 16:02:01

US3392049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'Yes (Y)'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 16:04:31

US3392049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered empty.	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 16:04:31

US3392049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered empty.	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 16:04:31

US3392049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 16:04:31

US3392049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '19 Aug 2020'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 16:04:31

US3392049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '11:00'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 16:04:31

US3392049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered '19 Aug 2020 11:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'Left Arm (LEFT ARM)'	(b) (4) Lois Eaglin (b) (4)	19 Aug 2020 16:04:31

US3392049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'ONCE'	System	19 Aug 2020 16:04:31

US3392049

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 16:04:31

US3392049

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:21:06

US3392049

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '19 Aug 2020'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:21:06

US3392049

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '10:30'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:21:06

US3392049

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered '19 Aug 2020 10:30'	System	28 Aug 2020 13:21:06

US3392049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:22:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '19 Aug 2020'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:21:42

US3392049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brandon Illickal (b) (4)	28 Aug 2020 13:21:42

US3392049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:21:42

US3392049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered '10:25'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:21:42

US3392049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered '19 Aug 2020 10:25'	System	28 Aug 2020 13:21:42

US3392049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brandon Illickal (b) (4)	28 Aug 2020 13:21:42

US3392049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:21:42

US3392049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered empty.	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:21:42

US3392049

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered empty.	System	28 Aug 2020 13:21:42

US3392049

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:47:24
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:21:46

US3392049

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'I'	System	28 Aug 2020 13:21:46

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-19T11:28:13', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'b676b02c-6f38-48fb-b69b-24dc962bcb66'	System	19 Aug 2020 16:28:47
User entered 'Yes (Y)'	System	19 Aug 2020 16:28:47

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-19T11:28:26', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'b676b02c-6f38-48fb-b69b-24dc962bcb66' User entered '97.3'	System	19 Aug 2020 16:28:47
	System	19 Aug 2020 16:28:47

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-19T11:28:33', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'b676b02c-6f38-48fb-b69b-24dc962bcb66'	System	19 Aug 2020 16:28:47
User entered 'No (N)'	System	19 Aug 2020 16:28:47

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-19T11:28:42', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'b676b02c-6f38-48fb-b69b-24dc962bcb66'	System	19 Aug 2020 16:28:47
User entered '19 Aug 2020 11:28'	System	19 Aug 2020 16:28:47

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '19 Aug 2020 11:20'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '19 Aug 2020 13:50'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '19 Aug 2020 14:45'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 2'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-20T14:00:38', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '0a9bd7b3-754c-408e-ad7d-81fccf12c022'	System	20 Aug 2020 19:00:50
User entered 'No (N)'	System	20 Aug 2020 19:00:50

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-20T14:00:42', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '0a9bd7b3-754c-408e-ad7d-81fccf12c022'	System	20 Aug 2020 19:00:50
User entered 'No (N)'	System	20 Aug 2020 19:00:50

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-20T14:00:48', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '0a9bd7b3-754c-408e-ad7d-81fccf12c022' User entered '20 Aug 2020 14:00'	System	20 Aug 2020 19:00:50
	System	20 Aug 2020 19:00:50

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 3'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-21T20:30:21', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e08b3915-b11a-456b-ba0c-894c18b9d70a' User entered 'Yes (Y)'	System	22 Aug 2020 01:30:43
	System	22 Aug 2020 01:30:43

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-21T20:30:29', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e08b3915-b11a-456b-ba0c-894c18b9d70a' User entered '97.8'	System	22 Aug 2020 01:30:43
	System	22 Aug 2020 01:30:43

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-21T20:30:33', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e08b3915-b11a-456b-ba0c-894c18b9d70a' User entered 'No (N)'	System	22 Aug 2020 01:30:43
	System	22 Aug 2020 01:30:43

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-21T20:30:39', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e08b3915-b11a-456b-ba0c-894c18b9d70a' User entered '21 Aug 2020 20:30'	System	22 Aug 2020 01:30:43
	System	22 Aug 2020 01:30:43

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 4'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-22T15:23:25', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a8627cd8-fa9c-48b1-b861-4bdbf183cfa5' User entered 'Yes (Y)'	System	22 Aug 2020 20:23:42
	System	22 Aug 2020 20:23:42

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-22T15:23:32', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a8627cd8-fa9c-48b1-b861-4bdbf183cfa5' User entered '97.8'	System	22 Aug 2020 20:23:42
	System	22 Aug 2020 20:23:42

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-22T15:23:38', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a8627cd8-fa9c-48b1-b861-4bdbf183cfa5'	System	22 Aug 2020 20:23:42
User entered 'No (N)'	System	22 Aug 2020 20:23:42

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-22T15:23:41', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a8627cd8-fa9c-48b1-b861-4bdbf183cfa5' User entered '22 Aug 2020 15:23'	System	22 Aug 2020 20:23:42
	System	22 Aug 2020 20:23:42

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 5'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-23T16:30:45', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '5c0338aa-7723-41f6-a192-d82260ccb3'	System	23 Aug 2020 21:31:08
User entered 'Yes (Y)'	System	23 Aug 2020 21:31:08

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-23T16:30:54', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '5c0338aa-7723-41f6-a192-d82260ccbbc3' User entered '97.8'	System	23 Aug 2020 21:31:08
	System	23 Aug 2020 21:31:08

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-23T16:31:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '5c0338aa-7723-41f6-a192-d82260ccb3'	System	23 Aug 2020 21:31:08
User entered 'No (N)'	System	23 Aug 2020 21:31:08

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-23T16:31:03', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '5c0338aa-7723-41f6-a192-d82260ccb3'	System	23 Aug 2020 21:31:08
User entered '23 Aug 2020 16:31'	System	23 Aug 2020 21:31:08

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 6'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-24T13:05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '449492a2-b063-4016-af7c-16e8e840575f' User entered 'Yes (Y)'	System	24 Aug 2020 18:05:27
	System	24 Aug 2020 18:05:27

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-24T13:05:13', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '449492a2-b063-4016-af7c-16e8e840575f' User entered '97.3'	System	24 Aug 2020 18:05:27
	System	24 Aug 2020 18:05:27

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-24T13:05:17', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '449492a2-b063-4016-af7c-16e8e840575f' User entered 'No (N)'	System	24 Aug 2020 18:05:27
	System	24 Aug 2020 18:05:27

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-24T13:05:23', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '449492a2-b063-4016-af7c-16e8e840575f' User entered '24 Aug 2020 13:05'	System	24 Aug 2020 18:05:27
	System	24 Aug 2020 18:05:27

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 7'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-25T12:00:23', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '71adec1a-4515-4396-a424-bb7c69256a26' User entered 'Yes (Y)'	System	25 Aug 2020 17:00:44
	System	25 Aug 2020 17:00:44

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-25T12:00:29', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '71adec1a-4515-4396-a424-bb7c69256a26' User entered '97.2'	System	25 Aug 2020 17:00:44
	System	25 Aug 2020 17:00:44

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-25T12:00:34', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '71adec1a-4515-4396-a424-bb7c69256a26' User entered 'No (N)'	System	25 Aug 2020 17:00:44
	System	25 Aug 2020 17:00:44

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-25T12:00:38', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '71adec1a-4515-4396-a424-bb7c69256a26' User entered '25 Aug 2020 12:00'	System	25 Aug 2020 17:00:44
	System	25 Aug 2020 17:00:44

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-19T11:29:15', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'adf9a254-fcc6-4b22-9fc3-e03d9f270f5a'	System	19 Aug 2020 16:29:37
User entered 'None (1)'	System	19 Aug 2020 16:29:37

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-19T11:29:22', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'adf9a254-fcc6-4b22-9fc3-e03d9f270f5a'	System	19 Aug 2020 16:29:37
User entered 'No (N)'	System	19 Aug 2020 16:29:37

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-19T11:29:25', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'adf9a254-fcc6-4b22-9fc3-e03d9f270f5a'	System	19 Aug 2020 16:29:37
User entered 'No (N)'	System	19 Aug 2020 16:29:37

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-19T11:29:29', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'adf9a254-fcc6-4b22-9fc3-e03d9f270f5a'	System	19 Aug 2020 16:29:37
User entered 'None (1)'	System	19 Aug 2020 16:29:37

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-19T11:29:33', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'adf9a254-fcc6-4b22-9fc3-e03d9f270f5a' User entered '19 Aug 2020 11:29'	System	19 Aug 2020 16:29:37
	System	19 Aug 2020 16:29:37

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '19 Aug 2020 11:20'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '19 Aug 2020 13:50'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '19 Aug 2020 14:45'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 2'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-20T14:00:56', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '8f9b0d8c-0754-4714-8628-d51bf232d524'	System	20 Aug 2020 19:01:15
User entered 'None (1)'	System	20 Aug 2020 19:01:15

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-20T14:00:59', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '8f9b0d8c-0754-4714-8628-d51bf232d524' User entered 'No (N)'	System	20 Aug 2020 19:01:15
	System	20 Aug 2020 19:01:15

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-20T14:01:03', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '8f9b0d8c-0754-4714-8628-d51bf232d524'	System	20 Aug 2020 19:01:15
User entered 'No (N)'	System	20 Aug 2020 19:01:15

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-20T14:01:08', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '8f9b0d8c-0754-4714-8628-d51bf232d524'	System	20 Aug 2020 19:01:15
User entered 'None (1)'	System	20 Aug 2020 19:01:15

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-20T14:01:11', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '8f9b0d8c-0754-4714-8628-d51bf232d524' User entered '20 Aug 2020 14:01'	System	20 Aug 2020 19:01:15
	System	20 Aug 2020 19:01:15

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 3'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-21T20:30:45', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '2fced312-bd4e-4a0d-a931-94ef1410589a'	System	22 Aug 2020 01:31:06
User entered 'None (1)'	System	22 Aug 2020 01:31:06

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-21T20:30:50', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '2fcd312-bd4e-4a0d-a931-94ef1410589a'	System	22 Aug 2020 01:31:06
User entered 'No (N)'	System	22 Aug 2020 01:31:06

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-21T20:30:53', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '2fcd312-bd4e-4a0d-a931-94ef1410589a'	System	22 Aug 2020 01:31:06
User entered 'No (N)'	System	22 Aug 2020 01:31:06

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-21T20:31:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '2fced312-bd4e-4a0d-a931-94ef1410589a'	System	22 Aug 2020 01:31:06
User entered 'None (1)'	System	22 Aug 2020 01:31:06

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-21T20:31:03', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '2fced312-bd4e-4a0d-a931-94ef1410589a' User entered '21 Aug 2020 20:31'	System	22 Aug 2020 01:31:06
	System	22 Aug 2020 01:31:06

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 4'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-22T15:23:48', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '07292ee2-a7d6-4925-bea7-7d089cee2b38' User entered 'None (1)'	System	22 Aug 2020 20:24:15
	System	22 Aug 2020 20:24:15

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-22T15:23:57', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '07292ee2-a7d6-4925-bea7-7d089cee2b38'	System	22 Aug 2020 20:24:15
User entered 'No (N)'	System	22 Aug 2020 20:24:15

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-22T15:24:05', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '07292ee2-a7d6-4925-bea7-7d089cee2b38' User entered 'No (N)'	System	22 Aug 2020 20:24:15
	System	22 Aug 2020 20:24:15

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-22T15:24:10', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '07292ee2-a7d6-4925-bea7-7d089cee2b38'	System	22 Aug 2020 20:24:15
User entered 'None (1)'	System	22 Aug 2020 20:24:15

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-22T15:24:13', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '07292ee2-a7d6-4925-bea7-7d089cee2b38' User entered '22 Aug 2020 15:24'	System	22 Aug 2020 20:24:15
	System	22 Aug 2020 20:24:15

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 5'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-23T16:31:07', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd5a0c66a-9425-4951-8627-1a05edfefe98'	System	23 Aug 2020 21:31:58
User entered 'None (1)'	System	23 Aug 2020 21:31:58

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-23T16:31:22', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd5a0c66a-9425-4951-8627-1a05edfefe98'	System	23 Aug 2020 21:31:58
User entered 'No (N)'	System	23 Aug 2020 21:31:58

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-23T16:31:49', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd5a0c66a-9425-4951-8627-1a05edfefe98'	System	23 Aug 2020 21:31:58
User entered 'No (N)'	System	23 Aug 2020 21:31:58

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-23T16:31:53', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd5a0c66a-9425-4951-8627-1a05edfefe98'	System	23 Aug 2020 21:31:58
User entered 'None (1)'	System	23 Aug 2020 21:31:58

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-23T16:31:56', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd5a0c66a-9425-4951-8627-1a05edfefe98' User entered '23 Aug 2020 16:31'	System	23 Aug 2020 21:31:58
	System	23 Aug 2020 21:31:58

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 6'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-24T13:05:28', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '5d2ad5de-d79a-459a-9cdf-2eac5407b988'	System	24 Aug 2020 18:05:42
User entered 'None (1)'	System	24 Aug 2020 18:05:42

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-24T13:05:31', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '5d2ad5de-d79a-459a-9cdf-2eac5407b988' User entered 'No (N)'	System	24 Aug 2020 18:05:42
	System	24 Aug 2020 18:05:42

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-24T13:05:34', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '5d2ad5de-d79a-459a-9cdf-2eac5407b988'	System	24 Aug 2020 18:05:42
User entered 'No (N)'	System	24 Aug 2020 18:05:42

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-24T13:05:36', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '5d2ad5de-d79a-459a-9cdf-2eac5407b988'	System	24 Aug 2020 18:05:42
User entered 'None (1)'	System	24 Aug 2020 18:05:42

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-24T13:05:39', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '5d2ad5de-d79a-459a-9cdf-2eac5407b988' User entered '24 Aug 2020 13:05'	System	24 Aug 2020 18:05:42
	System	24 Aug 2020 18:05:42

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 7'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-25T12:00:46', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '162106f2-ecfa-44f7-8e2b-d7d281eda30f'	System	25 Aug 2020 17:01:15
User entered 'None (1)'	System	25 Aug 2020 17:01:15

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-25T12:00:50', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '162106f2-ecfa-44f7-8e2b-d7d281eda30f' User entered 'No (N)'	System	25 Aug 2020 17:01:15
	System	25 Aug 2020 17:01:15

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-25T12:00:53', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '162106f2-ecfa-44f7-8e2b-d7d281eda30f'	System	25 Aug 2020 17:01:15
User entered 'No (N)'	System	25 Aug 2020 17:01:15

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-25T12:00:56', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '162106f2-ecfa-44f7-8e2b-d7d281eda30f'	System	25 Aug 2020 17:01:15
User entered 'None (1)'	System	25 Aug 2020 17:01:15

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-25T12:01:01', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '162106f2-ecfa-44f7-8e2b-d7d281eda30f' User entered '25 Aug 2020 12:01'	System	25 Aug 2020 17:01:15
	System	25 Aug 2020 17:01:15

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-19T11:29:39', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '3644bcf9-b9a0-45ca-a25e-606fbb944faf' User entered 'None (0)'	System	19 Aug 2020 16:30:07
	System	19 Aug 2020 16:30:07

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-19T11:29:42', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '3644bcf9-b9a0-45ca-a25e-606fbb944faf' User entered 'None (0)'	System	19 Aug 2020 16:30:07
	System	19 Aug 2020 16:30:07

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-19T11:29:45', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '3644bcf9-b9a0-45ca-a25e-606fbb944faf' User entered 'None (0)'	System	19 Aug 2020 16:30:07
	System	19 Aug 2020 16:30:07

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-19T11:29:48', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '3644bcf9-b9a0-45ca-a25e-606fbb944faf' User entered 'None (0)'	System	19 Aug 2020 16:30:07
	System	19 Aug 2020 16:30:07

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-19T11:29:51', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '3644bcf9-b9a0-45ca-a25e-606fbb944faf' User entered 'None (0)'	System	19 Aug 2020 16:30:07
	System	19 Aug 2020 16:30:07

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-19T11:29:54', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '3644bcf9-b9a0-45ca-a25e-606fbb944faf' User entered 'None (0)'	System	19 Aug 2020 16:30:07
	System	19 Aug 2020 16:30:07

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-19T11:29:58', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '3644bcf9-b9a0-45ca-a25e-606fbb944faf' User entered 'No (N)'	System	19 Aug 2020 16:30:07
	System	19 Aug 2020 16:30:07

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-19T11:30:01', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '3644bcf9-b9a0-45ca-a25e-606fbb944faf' User entered '19 Aug 2020 11:30'	System	19 Aug 2020 16:30:07
	System	19 Aug 2020 16:30:07

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '19 Aug 2020 11:20'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '19 Aug 2020 13:50'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '19 Aug 2020 14:45'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 2'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-20T14:01:16', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd758a530-0832-4136-8e4b-7258b61c0ec6' User entered 'None (0)'	System	20 Aug 2020 19:01:42
	System	20 Aug 2020 19:01:42

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-20T14:01:18', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd758a530-0832-4136-8e4b-7258b61c0ec6' User entered 'None (0)'	System	20 Aug 2020 19:01:42
	System	20 Aug 2020 19:01:42

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-20T14:01:21', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd758a530-0832-4136-8e4b-7258b61c0ec6' User entered 'None (0)'	System	20 Aug 2020 19:01:42
	System	20 Aug 2020 19:01:42

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-20T14:01:24', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd758a530-0832-4136-8e4b-7258b61c0ec6' User entered 'None (0)'	System	20 Aug 2020 19:01:42
	System	20 Aug 2020 19:01:42

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-20T14:01:27', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd758a530-0832-4136-8e4b-7258b61c0ec6'	System	20 Aug 2020 19:01:42
User entered 'None (0)'	System	20 Aug 2020 19:01:42

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-20T14:01:29', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd758a530-0832-4136-8e4b-7258b61c0ec6' User entered 'None (0)'	System	20 Aug 2020 19:01:42
	System	20 Aug 2020 19:01:42

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-20T14:01:33', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd758a530-0832-4136-8e4b-7258b61c0ec6'	System	20 Aug 2020 19:01:42
User entered 'No (N)'	System	20 Aug 2020 19:01:42

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-20T14:01:36', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd758a530-0832-4136-8e4b-7258b61c0ec6' User entered '20 Aug 2020 14:01'	System	20 Aug 2020 19:01:42
	System	20 Aug 2020 19:01:42

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 3'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-21T20:31:08', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '332365b9-4d85-40b2-a3b5-bb4f9221d993'	System	22 Aug 2020 01:31:29
User entered 'None (0)'	System	22 Aug 2020 01:31:29

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-21T20:31:10', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '332365b9-4d85-40b2-a3b5-bb4f9221d993'	System	22 Aug 2020 01:31:29
User entered 'None (0)'	System	22 Aug 2020 01:31:29

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-21T20:31:13', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '332365b9-4d85-40b2-a3b5-bb4f9221d993'	System	22 Aug 2020 01:31:29
User entered 'None (0)'	System	22 Aug 2020 01:31:29

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-21T20:31:15', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '332365b9-4d85-40b2-a3b5-bb4f9221d993'	System	22 Aug 2020 01:31:29
User entered 'None (0)'	System	22 Aug 2020 01:31:29

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-21T20:31:18', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '332365b9-4d85-40b2-a3b5-bb4f9221d993' User entered 'None (0)'	System	22 Aug 2020 01:31:29
	System	22 Aug 2020 01:31:29

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-21T20:31:20', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '332365b9-4d85-40b2-a3b5-bb4f9221d993'	System	22 Aug 2020 01:31:29
User entered 'None (0)'	System	22 Aug 2020 01:31:29

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-21T20:31:23', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '332365b9-4d85-40b2-a3b5-bb4f9221d993'	System	22 Aug 2020 01:31:29
User entered 'No (N)'	System	22 Aug 2020 01:31:29

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-21T20:31:26', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '332365b9-4d85-40b2-a3b5-bb4f9221d993' User entered '21 Aug 2020 20:31'	System	22 Aug 2020 01:31:29
	System	22 Aug 2020 01:31:29

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 4'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-22T15:24:18', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '2b8cc9f1-0420-4d02-b91e-8f8e7b3a1e25' User entered 'None (0)'	System	22 Aug 2020 20:24:41
	System	22 Aug 2020 20:24:41

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-22T15:24:20', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '2b8cc9f1-0420-4d02-b91e-8f8e7b3a1e25' User entered 'None (0)'	System	22 Aug 2020 20:24:41
	System	22 Aug 2020 20:24:41

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-22T15:24:22', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '2b8cc9f1-0420-4d02-b91e-8f8e7b3a1e25' User entered 'None (0)'	System	22 Aug 2020 20:24:41
	System	22 Aug 2020 20:24:41

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-22T15:24:25', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '2b8cc9f1-0420-4d02-b91e-8f8e7b3a1e25' User entered 'None (0)'	System	22 Aug 2020 20:24:41
	System	22 Aug 2020 20:24:41

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-22T15:24:27', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '2b8cc9f1-0420-4d02-b91e-8f8e7b3a1e25' User entered 'None (0)'	System	22 Aug 2020 20:24:41
	System	22 Aug 2020 20:24:41

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-22T15:24:30', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '2b8cc9f1-0420-4d02-b91e-8f8e7b3a1e25' User entered 'None (0)'	System	22 Aug 2020 20:24:41
	System	22 Aug 2020 20:24:41

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-22T15:24:37', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '2b8cc9f1-0420-4d02-b91e-8f8e7b3a1e25'	System	22 Aug 2020 20:24:41
User entered 'No (N)'	System	22 Aug 2020 20:24:41

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-22T15:24:39', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '2b8cc9f1-0420-4d02-b91e-8f8e7b3a1e25' User entered '22 Aug 2020 15:24'	System	22 Aug 2020 20:24:41
	System	22 Aug 2020 20:24:41

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 5'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-23T16:32:01', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '9ce22a92-dc50-4abe-b3e9-9b8a47af4fde' User entered 'None (0)'	System	23 Aug 2020 21:32:34
	System	23 Aug 2020 21:32:34

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-23T16:32:03', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '9ce22a92-dc50-4abe-b3e9-9b8a47af4fde' User entered 'None (0)'	System	23 Aug 2020 21:32:34
	System	23 Aug 2020 21:32:34

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-23T16:32:06', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '9ce22a92-dc50-4abe-b3e9-9b8a47af4fde' User entered 'None (0)'	System	23 Aug 2020 21:32:34
	System	23 Aug 2020 21:32:34

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-23T16:32:09', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '9ce22a92-dc50-4abe-b3e9-9b8a47af4fde' User entered 'None (0)'	System	23 Aug 2020 21:32:34
	System	23 Aug 2020 21:32:34

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-23T16:32:12', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '9ce22a92-dc50-4abe-b3e9-9b8a47af4fde' User entered 'None (0)'	System	23 Aug 2020 21:32:34
	System	23 Aug 2020 21:32:34

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-23T16:32:14', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '9ce22a92-dc50-4abe-b3e9-9b8a47af4fde' User entered 'None (0)'	System	23 Aug 2020 21:32:34
	System	23 Aug 2020 21:32:34

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-23T16:32:26', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '9ce22a92-dc50-4abe-b3e9-9b8a47af4fde' User entered 'No (N)'	System	23 Aug 2020 21:32:34
	System	23 Aug 2020 21:32:34

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-23T16:32:30', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '9ce22a92-dc50-4abe-b3e9-9b8a47af4fde' User entered '23 Aug 2020 16:32'	System	23 Aug 2020 21:32:34
	System	23 Aug 2020 21:32:34

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 6'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-24T13:05:43', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '93921b7c-b8ce-4137-a73d-d05db1079915' User entered 'None (0)'	System	24 Aug 2020 18:06:12
	System	24 Aug 2020 18:06:12

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-24T13:05:46', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '93921b7c-b8ce-4137-a73d-d05db1079915' User entered 'None (0)'	System	24 Aug 2020 18:06:12
	System	24 Aug 2020 18:06:12

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-24T13:05:50', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '93921b7c-b8ce-4137-a73d-d05db1079915' User entered 'None (0)'	System	24 Aug 2020 18:06:12
	System	24 Aug 2020 18:06:12

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-24T13:05:53', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '93921b7c-b8ce-4137-a73d-d05db1079915' User entered 'None (0)'	System	24 Aug 2020 18:06:12
	System	24 Aug 2020 18:06:12

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-24T13:05:56', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '93921b7c-b8ce-4137-a73d-d05db1079915' User entered 'None (0)'	System	24 Aug 2020 18:06:12
	System	24 Aug 2020 18:06:12

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-24T13:05:59', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '93921b7c-b8ce-4137-a73d-d05db1079915' User entered 'None (0)'	System	24 Aug 2020 18:06:12
	System	24 Aug 2020 18:06:12

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-24T13:06:06', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '93921b7c-b8ce-4137-a73d-d05db1079915'	System	24 Aug 2020 18:06:12
User entered 'No (N)'	System	24 Aug 2020 18:06:12

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-24T13:06:08', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '93921b7c-b8ce-4137-a73d-d05db1079915' User entered '24 Aug 2020 13:06'	System	24 Aug 2020 18:06:12
	System	24 Aug 2020 18:06:12

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 7'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-25T12:01:05', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'ff3a28e7-b5d1-43d3-9ffe-8224a2198b95'	System	25 Aug 2020 17:01:44
User entered 'None (0)'	System	25 Aug 2020 17:01:44

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-25T12:01:08', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'ff3a28e7-b5d1-43d3-9ffe-8224a2198b95'	System	25 Aug 2020 17:01:44
User entered 'None (0)'	System	25 Aug 2020 17:01:44

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-25T12:01:11', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'ff3a28e7-b5d1-43d3-9ffe-8224a2198b95'	System	25 Aug 2020 17:01:44
User entered 'None (0)'	System	25 Aug 2020 17:01:44

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-25T12:01:16', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'ff3a28e7-b5d1-43d3-9ffe-8224a2198b95'	System	25 Aug 2020 17:01:44
User entered 'None (0)'	System	25 Aug 2020 17:01:44

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-25T12:01:20', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'ff3a28e7-b5d1-43d3-9ffe-8224a2198b95'	System	25 Aug 2020 17:01:44
User entered 'None (0)'	System	25 Aug 2020 17:01:44

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-25T12:01:23', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'ff3a28e7-b5d1-43d3-9ffe-8224a2198b95'	System	25 Aug 2020 17:01:44
User entered 'None (0)'	System	25 Aug 2020 17:01:44

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-25T12:01:27', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'ff3a28e7-b5d1-43d3-9ffe-8224a2198b95'	System	25 Aug 2020 17:01:44
User entered 'No (N)'	System	25 Aug 2020 17:01:44

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-08-25T12:01:30', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'ff3a28e7-b5d1-43d3-9ffe-8224a2198b95'	System	25 Aug 2020 17:01:44
User entered '25 Aug 2020 12:01'	System	25 Aug 2020 17:01:44

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 16:04:31

US3392049

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:01:38
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:30

US3392049

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:01:38
User entered '26 Aug 2020'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:30

US3392049

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:01:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:30

US3392049

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:01:38
User entered empty.	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:30

US3392049

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:01:38
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Aug 2020 13:22:59

US3392049

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'I'	System	28 Aug 2020 13:22:59

US3392049

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 02:28:15
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	03 Sep 2020 13:00:34

US3392049

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:28:15
User entered '2 Sep 2020'	(b) (4) Brandon Illickal (b) (4)	03 Sep 2020 13:00:34

US3392049

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:28:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Brandon Illickal (b) (4)	03 Sep 2020 13:00:34

US3392049

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:28:15
User entered empty.	(b) (4) Brandon Illickal (b) (4)	03 Sep 2020 13:00:34

US3392049

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:28:15
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	09 Sep 2020 23:44:51

US3392049

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered '1'	System	09 Sep 2020 23:44:51

US3392049

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:08:50
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	14 Sep 2020 16:26:12

US3392049

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:08:50
User entered '9 Sep 2020'	(b) (4) Brandon Illickal (b) (4)	14 Sep 2020 16:26:12

US3392049

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 02:08:50
User entered 'Contact Made (CONTACT MADE)'	Brandon Illickal (b) (4) (b) (4)	14 Sep 2020 16:26:12

US3392049

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:08:50
User entered empty.	(b) (4) Brandon Illickal (b) (4)	14 Sep 2020 16:26:12

US3392049

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 02:08:50
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	14 Sep 2020 16:26:18

US3392049

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered '1'	System	14 Sep 2020 16:26:18

US3392049

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	14 Sep 2020 16:26:30

US3392049

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
Amendment Manager: User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	17 Sep 2020 00:13:43
Amendment Manager: Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	17 Sep 2020 00:13:43
Amendment Manager: Query text changed to "Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates."	System	17 Sep 2020 00:13:43
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	14 Sep 2020 16:26:30
User entered '14 Sep 2020'	Brandon Illickal (b) (4)	14 Sep 2020 16:26:30

US3392049

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered 'Clinic (Clinic)'	(b) (4) Brandon Illickal (b) (4)	14 Sep 2020 16:26:30

US3392049

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'VISIT2'	System	14 Sep 2020 16:26:30

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Lawson (b) (4) (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '14 Sep 2020'	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '10:12'	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered '14 Sep 2020 10:12'	System	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '98.4' F	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered 'Oral (Oral)'	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered empty.	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '77'	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'bpm'	System	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '10'	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'breaths/min'	System	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '138'	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'mmHg'	System	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '89'	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'mmHg'	System	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Lawson (b) (4) (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '14 Sep 2020'	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '11:44'	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered '14 Sep 2020 11:44'	System	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '98.6' F	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered 'Oral (Oral)'	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered empty.	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '79'	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'bpm'	System	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '16'	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'breaths/min'	System	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '142'	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'mmHg'	System	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '88'	Brenda Lawson (b) (4)	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'mmHg'	System	21 Sep 2020 21:54:40

US3392049

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	21 Sep 2020 21:54:49

US3392049

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '14 Sep 2020'	Brenda Lawson (b) (4)	21 Sep 2020 21:54:49

US3392049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	14 Sep 2020 16:26:51

US3392049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered empty.	(b) (4) Brandon Illickal (b) (4)	14 Sep 2020 16:26:51

US3392049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered empty.	(b) (4) Brandon Illickal (b) (4)	14 Sep 2020 16:26:51

US3392049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 16:26:51

US3392049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '14 Sep 2020'	(b) (4) Brandon Illickal (b) (4)	14 Sep 2020 16:26:51

US3392049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '11:12'	(b) (4) Brandon Illickal (b) (4)	14 Sep 2020 16:26:51

US3392049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered '14 Sep 2020 11:12'	System	14 Sep 2020 16:26:51

US3392049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered 'Left Arm (LEFT ARM)'	(b) (4) Brandon Illickal (b) (4)	14 Sep 2020 16:26:51

US3392049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'ONCE'	System	14 Sep 2020 16:26:51

US3392049

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 16:26:51

US3392049

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	21 Sep 2020 21:55:33

US3392049

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '14 Sep 2020'	Brenda Lawson (b) (4)	21 Sep 2020 21:55:33

US3392049

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '10:30'	Brenda Lawson (b) (4)	21 Sep 2020 21:55:33

US3392049

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered '14 Sep 2020 10:30'	System	21 Sep 2020 21:55:33

US3392049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:22:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '14 Sep 2020'	Brenda Lawson (b) (4)	21 Sep 2020 21:55:57

US3392049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Lawson (b) (4) (b) (4)	21 Sep 2020 21:55:57

US3392049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	21 Sep 2020 21:55:57

US3392049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered '10:27'	Brenda Lawson (b) (4)	21 Sep 2020 21:55:57

US3392049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered '14 Sep 2020 10:27'	System	21 Sep 2020 21:55:57

US3392049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Lawson (b) (4) (b) (4)	21 Sep 2020 21:55:57

US3392049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered 'No (N)'	Brenda Lawson (b) (4)	21 Sep 2020 21:55:57

US3392049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered empty.	Brenda Lawson (b) (4)	21 Sep 2020 21:55:57

US3392049

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered empty.	System	21 Sep 2020 21:55:57

US3392049

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:36:32
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	21 Sep 2020 19:56:31

US3392049

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered '1'	System	21 Sep 2020 19:56:31

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T11:49:33', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '21dfddb-1f12-484f-beca-d74d38261302'	System	14 Sep 2020 16:49:54
User entered 'Yes (Y)'	System	14 Sep 2020 16:49:54

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T11:49:39', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '21dfddb-1f12-484f-beca-d74d38261302' User entered '98.6'	System	14 Sep 2020 16:49:54
	System	14 Sep 2020 16:49:54

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T11:49:44', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '21dfddb-1f12-484f-beca-d74d38261302'	System	14 Sep 2020 16:49:54
User entered 'No (N)'	System	14 Sep 2020 16:49:54

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T11:49:50', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '21dfddb-1f12-484f-beca-d74d38261302' User entered '14 Sep 2020 11:49'	System	14 Sep 2020 16:49:54
	System	14 Sep 2020 16:49:54

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '14 Sep 2020 11:32'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '14 Sep 2020 14:02'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T17:05:37', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a42a18cb-37aa-4032-a47f-b2d20ac15214' User entered 'Yes (Y)'	System	14 Sep 2020 22:05:55
	System	14 Sep 2020 22:05:55

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T17:05:42', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a42a18cb-37aa-4032-a47f-b2d20ac15214' User entered '97.8'	System	14 Sep 2020 22:05:55
	System	14 Sep 2020 22:05:55

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T17:05:49', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a42a18cb-37aa-4032-a47f-b2d20ac15214'	System	14 Sep 2020 22:05:55
User entered 'No (N)'	System	14 Sep 2020 22:05:55

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T17:05:52', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a42a18cb-37aa-4032-a47f-b2d20ac15214' User entered '14 Sep 2020 17:05'	System	14 Sep 2020 22:05:55
	System	14 Sep 2020 22:05:55

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '14 Sep 2020 14:57'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 2'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-15T12:00:36', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '6955d026-8943-491b-88dc-72a3635578a2'	System	15 Sep 2020 17:00:58
User entered 'No (N)'	System	15 Sep 2020 17:00:58

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-15T12:00:39', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '6955d026-8943-491b-88dc-72a3635578a2'	System	15 Sep 2020 17:00:58
User entered 'No (N)'	System	15 Sep 2020 17:00:58

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-15T12:00:42', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '6955d026-8943-491b-88dc-72a3635578a2'	System	15 Sep 2020 17:00:58
User entered '15 Sep 2020 12:00'	System	15 Sep 2020 17:00:58

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 3'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T09:49:05', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'cdbde6a1-0141-403d-ae08-98d1afda2aea' User entered 'No (N)'	System	17 Sep 2020 14:49:19
	System	17 Sep 2020 14:49:19

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T09:49:10', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'cdbde6a1-0141-403d-ae08-98d1afda2aea' User entered 'No (N)'	System	17 Sep 2020 14:49:19
	System	17 Sep 2020 14:49:19

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T09:49:15', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'cdbde6a1-0141-403d-ae08-98d1afda2aea' User entered '17 Sep 2020 09:49'	System	17 Sep 2020 14:49:19
	System	17 Sep 2020 14:49:19

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 4'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T12:01:22', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a6d316f6-5834-4e22-8504-2375a31017e9' User entered 'No (N)'	System	17 Sep 2020 17:02:26
	System	17 Sep 2020 17:02:26

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T12:01:26', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a6d316f6-5834-4e22-8504-2375a31017e9' User entered 'No (N)'	System	17 Sep 2020 17:02:26
	System	17 Sep 2020 17:02:26

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T12:01:29', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a6d316f6-5834-4e22-8504-2375a31017e9' User entered '17 Sep 2020 12:01'	System	17 Sep 2020 17:02:26
	System	17 Sep 2020 17:02:26

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 5'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T07:15:51', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '46bd8006-a4cf-43b9-94af-162fb0997f91'	System	19 Sep 2020 12:16:12
User entered 'Yes (Y)'	System	19 Sep 2020 12:16:12

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T07:15:59', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '46bd8006-a4cf-43b9-94af-162fb0997f91' User entered '97.5'	System	19 Sep 2020 12:16:12
	System	19 Sep 2020 12:16:12

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T07:16:04', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '46bd8006-a4cf-43b9-94af-162fb0997f91'	System	19 Sep 2020 12:16:12
User entered 'No (N)'	System	19 Sep 2020 12:16:12

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T07:16:09', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '46bd8006-a4cf-43b9-94af-162fb0997f91' User entered '19 Sep 2020 07:16'	System	19 Sep 2020 12:16:12
	System	19 Sep 2020 12:16:12

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 6'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T12:01:17', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '843ebbd7-f739-411d-a813-74b64bca53fb' User entered 'Yes (Y)'	System	19 Sep 2020 17:01:53
	System	19 Sep 2020 17:01:53

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T12:01:23', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '843ebbd7-f739-411d-a813-74b64bca53fb' User entered '97.8'	System	19 Sep 2020 17:01:53
	System	19 Sep 2020 17:01:53

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T12:01:28', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '843ebbd7-f739-411d-a813-74b64bca53fb' User entered 'No (N)'	System	19 Sep 2020 17:01:53
	System	19 Sep 2020 17:01:53

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T12:01:31', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '843ebbd7-f739-411d-a813-74b64bca53fb' User entered '19 Sep 2020 12:01'	System	19 Sep 2020 17:01:53
	System	19 Sep 2020 17:01:53

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 7'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-20T12:00:29', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e756ac08-9917-46c5-a2de-1ef3ff84ee30' User entered 'Yes (Y)'	System	20 Sep 2020 17:00:53
	System	20 Sep 2020 17:00:53

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-20T12:00:36', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e756ac08-9917-46c5-a2de-1ef3ff84ee30' User entered '97.2'	System	20 Sep 2020 17:00:53
	System	20 Sep 2020 17:00:53

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-20T12:00:40', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e756ac08-9917-46c5-a2de-1ef3ff84ee30'	System	20 Sep 2020 17:00:53
User entered 'No (N)'	System	20 Sep 2020 17:00:53

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-20T12:00:45', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e756ac08-9917-46c5-a2de-1ef3ff84ee30' User entered '20 Sep 2020 12:00'	System	20 Sep 2020 17:00:53
	System	20 Sep 2020 17:00:53

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T11:49:57', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '076942d6-013a-4e22-ad7c-c90e1868658f' User entered 'None (1)'	System	14 Sep 2020 16:50:15
	System	14 Sep 2020 16:50:15

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T11:50:01', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '076942d6-013a-4e22-ad7c-c90e1868658f' User entered 'No (N)'	System	14 Sep 2020 16:50:15
	System	14 Sep 2020 16:50:15

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T11:50:05', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '076942d6-013a-4e22-ad7c-c90e1868658f' User entered 'No (N)'	System	14 Sep 2020 16:50:15
	System	14 Sep 2020 16:50:15

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T11:50:09', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '076942d6-013a-4e22-ad7c-c90e1868658f' User entered 'None (1)'	System	14 Sep 2020 16:50:15
	System	14 Sep 2020 16:50:15

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T11:50:13', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '076942d6-013a-4e22-ad7c-c90e1868658f' User entered '14 Sep 2020 11:50'	System	14 Sep 2020 16:50:15
	System	14 Sep 2020 16:50:15

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '14 Sep 2020 11:32'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '14 Sep 2020 14:02'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T17:06:07', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '2eeadd6f-8055-4b36-b7eb-efab4c0199a4'	System	14 Sep 2020 22:06:25
User entered 'None (1)'	System	14 Sep 2020 22:06:25

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T17:06:12', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '2eeadd6f-8055-4b36-b7eb-efab4c0199a4'	System	14 Sep 2020 22:06:25
User entered 'No (N)'	System	14 Sep 2020 22:06:25

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T17:06:16', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '2eeadd6f-8055-4b36-b7eb-efab4c0199a4'	System	14 Sep 2020 22:06:25
User entered 'No (N)'	System	14 Sep 2020 22:06:25

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T17:06:20', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '2eeadd6f-8055-4b36-b7eb-efab4c0199a4'	System	14 Sep 2020 22:06:25
User entered 'None (1)'	System	14 Sep 2020 22:06:25

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T17:06:23', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '2eeadd6f-8055-4b36-b7eb-efab4c0199a4' User entered '14 Sep 2020 17:06'	System	14 Sep 2020 22:06:25
	System	14 Sep 2020 22:06:25

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '14 Sep 2020 14:57'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 2'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-15T12:00:48', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '1161a890-c2c4-4030-9101-f65a646600ef' User entered 'None (1)'	System	15 Sep 2020 17:01:44
	System	15 Sep 2020 17:01:44

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-15T12:00:51', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '1161a890-c2c4-4030-9101-f65a646600ef' User entered 'No (N)'	System	15 Sep 2020 17:01:44
	System	15 Sep 2020 17:01:44

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-15T12:00:54', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '1161a890-c2c4-4030-9101-f65a646600ef' User entered 'No (N)'	System	15 Sep 2020 17:01:44
	System	15 Sep 2020 17:01:44

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-15T12:00:57', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '1161a890-c2c4-4030-9101-f65a646600ef' User entered 'None (1)'	System	15 Sep 2020 17:01:44
	System	15 Sep 2020 17:01:44

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-15T12:01:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '1161a890-c2c4-4030-9101-f65a646600ef' User entered '15 Sep 2020 12:01'	System	15 Sep 2020 17:01:44
	System	15 Sep 2020 17:01:44

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 3'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T09:49:19', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '42c6c6dd-25ca-4dab-ac60-2cd332649cce' User entered 'None (1)'	System	17 Sep 2020 14:49:38
	System	17 Sep 2020 14:49:38

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T09:49:23', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '42c6c6dd-25ca-4dab-ac60-2cd332649cce' User entered 'No (N)'	System	17 Sep 2020 14:49:38
	System	17 Sep 2020 14:49:38

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T09:49:29', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '42c6c6dd-25ca-4dab-ac60-2cd332649cce' User entered 'No (N)'	System	17 Sep 2020 14:49:38
	System	17 Sep 2020 14:49:38

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T09:49:33', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '42c6c6dd-25ca-4dab-ac60-2cd332649cce' User entered 'None (1)'	System	17 Sep 2020 14:49:38
	System	17 Sep 2020 14:49:38

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T09:49:36', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '42c6c6dd-25ca-4dab-ac60-2cd332649cce' User entered '17 Sep 2020 09:49'	System	17 Sep 2020 14:49:38
	System	17 Sep 2020 14:49:38

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 4'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T12:01:34', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '59a95e75-610a-47d2-82c2-76772f6c3fa3'	System	17 Sep 2020 17:02:46
User entered 'None (1)'	System	17 Sep 2020 17:02:46

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T12:01:38', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '59a95e75-610a-47d2-82c2-76772f6c3fa3' User entered 'No (N)'	System	17 Sep 2020 17:02:46
	System	17 Sep 2020 17:02:46

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T12:01:42', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '59a95e75-610a-47d2-82c2-76772f6c3fa3'	System	17 Sep 2020 17:02:46
User entered 'No (N)'	System	17 Sep 2020 17:02:46

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T12:01:44', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '59a95e75-610a-47d2-82c2-76772f6c3fa3'	System	17 Sep 2020 17:02:46
User entered 'None (1)'	System	17 Sep 2020 17:02:46

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T12:01:47', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '59a95e75-610a-47d2-82c2-76772f6c3fa3' User entered '17 Sep 2020 12:01'	System	17 Sep 2020 17:02:46
	System	17 Sep 2020 17:02:46

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 5'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T07:16:14', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'b392f8c8-541d-4918-87ac-687421e704f3'	System	19 Sep 2020 12:16:28
User entered 'None (1)'	System	19 Sep 2020 12:16:28

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T07:16:17', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'b392f8c8-541d-4918-87ac-687421e704f3'	System	19 Sep 2020 12:16:28
User entered 'No (N)'	System	19 Sep 2020 12:16:28

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T07:16:20', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'b392f8c8-541d-4918-87ac-687421e704f3'	System	19 Sep 2020 12:16:28
User entered 'No (N)'	System	19 Sep 2020 12:16:28

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T07:16:22', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'b392f8c8-541d-4918-87ac-687421e704f3'	System	19 Sep 2020 12:16:28
User entered 'None (1)'	System	19 Sep 2020 12:16:28

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T07:16:25', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'b392f8c8-541d-4918-87ac-687421e704f3' User entered '19 Sep 2020 07:16'	System	19 Sep 2020 12:16:28
	System	19 Sep 2020 12:16:28

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 6'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T12:01:38', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '583a25ca-f6f0-478a-9253-2c40702364b3'	System	19 Sep 2020 17:02:14
User entered 'None (1)'	System	19 Sep 2020 17:02:14

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T12:01:42', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '583a25ca-f6f0-478a-9253-2c40702364b3' User entered 'No (N)'	System	19 Sep 2020 17:02:14
	System	19 Sep 2020 17:02:14

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T12:01:44', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '583a25ca-f6f0-478a-9253-2c40702364b3' User entered 'No (N)'	System	19 Sep 2020 17:02:14
	System	19 Sep 2020 17:02:14

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T12:01:46', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '583a25ca-f6f0-478a-9253-2c40702364b3'	System	19 Sep 2020 17:02:14
User entered 'None (1)'	System	19 Sep 2020 17:02:14

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T12:01:49', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '583a25ca-f6f0-478a-9253-2c40702364b3' User entered '19 Sep 2020 12:01'	System	19 Sep 2020 17:02:14
	System	19 Sep 2020 17:02:14

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 7'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-20T12:00:49', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd8e7b830-6a75-483b-b77a-dd41f46216ab' User entered 'None (1)'	System	20 Sep 2020 17:01:16
	System	20 Sep 2020 17:01:16

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-20T12:00:52', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd8e7b830-6a75-483b-b77a-dd41f46216ab' User entered 'No (N)'	System	20 Sep 2020 17:01:16
	System	20 Sep 2020 17:01:16

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-20T12:00:58', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd8e7b830-6a75-483b-b77a-dd41f46216ab' User entered 'No (N)'	System	20 Sep 2020 17:01:16
	System	20 Sep 2020 17:01:16

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-20T12:01:01', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd8e7b830-6a75-483b-b77a-dd41f46216ab' User entered 'None (1)'	System	20 Sep 2020 17:01:16
	System	20 Sep 2020 17:01:16

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-20T12:01:07', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd8e7b830-6a75-483b-b77a-dd41f46216ab' User entered '20 Sep 2020 12:01'	System	20 Sep 2020 17:01:16
	System	20 Sep 2020 17:01:16

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T11:50:17', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '914d4bc0-0656-4a5d-9ad3-331cc2bb33b8' User entered 'None (0)'	System	14 Sep 2020 16:50:39
	System	14 Sep 2020 16:50:39

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T11:50:20', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '914d4bc0-0656-4a5d-9ad3-331cc2bb33b8' User entered 'None (0)'	System	14 Sep 2020 16:50:39
	System	14 Sep 2020 16:50:39

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T11:50:22', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '914d4bc0-0656-4a5d-9ad3-331cc2bb33b8' User entered 'None (0)'	System	14 Sep 2020 16:50:39
	System	14 Sep 2020 16:50:39

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T11:50:24', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '914d4bc0-0656-4a5d-9ad3-331cc2bb33b8' User entered 'None (0)'	System	14 Sep 2020 16:50:39
	System	14 Sep 2020 16:50:39

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T11:50:26', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '914d4bc0-0656-4a5d-9ad3-331cc2bb33b8' User entered 'None (0)'	System	14 Sep 2020 16:50:39
	System	14 Sep 2020 16:50:39

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T11:50:28', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '914d4bc0-0656-4a5d-9ad3-331cc2bb33b8' User entered 'None (0)'	System	14 Sep 2020 16:50:39
	System	14 Sep 2020 16:50:39

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T11:50:32', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '914d4bc0-0656-4a5d-9ad3-331cc2bb33b8' User entered 'No (N)'	System	14 Sep 2020 16:50:39
	System	14 Sep 2020 16:50:39

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T11:50:34', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '914d4bc0-0656-4a5d-9ad3-331cc2bb33b8' User entered '14 Sep 2020 11:50'	System	14 Sep 2020 16:50:39
	System	14 Sep 2020 16:50:39

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '14 Sep 2020 11:32'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '14 Sep 2020 14:02'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T17:06:27', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a4fa35fc-fed1-4d0f-810f-d707f7834a1d' User entered 'None (0)'	System	14 Sep 2020 22:06:50
	System	14 Sep 2020 22:06:50

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T17:06:31', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a4fa35fc-fed1-4d0f-810f-d707f7834a1d' User entered 'None (0)'	System	14 Sep 2020 22:06:50
	System	14 Sep 2020 22:06:50

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T17:06:34', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a4fa35fc-fed1-4d0f-810f-d707f7834a1d' User entered 'None (0)'	System	14 Sep 2020 22:06:50
	System	14 Sep 2020 22:06:50

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T17:06:37', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a4fa35fc-fed1-4d0f-810f-d707f7834a1d' User entered 'None (0)'	System	14 Sep 2020 22:06:50
	System	14 Sep 2020 22:06:50

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T17:06:39', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a4fa35fc-fed1-4d0f-810f-d707f7834a1d' User entered 'None (0)'	System	14 Sep 2020 22:06:50
	System	14 Sep 2020 22:06:50

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T17:06:42', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a4fa35fc-fed1-4d0f-810f-d707f7834a1d' User entered 'None (0)'	System	14 Sep 2020 22:06:50
	System	14 Sep 2020 22:06:50

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T17:06:46', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a4fa35fc-fed1-4d0f-810f-d707f7834a1d' User entered 'No (N)'	System	14 Sep 2020 22:06:50
	System	14 Sep 2020 22:06:50

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-14T17:06:49', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a4fa35fc-fed1-4d0f-810f-d707f7834a1d' User entered '14 Sep 2020 17:06'	System	14 Sep 2020 22:06:50
	System	14 Sep 2020 22:06:50

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '14 Sep 2020 14:57'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 2'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-15T12:01:05', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '8c4f03ff-6b35-47b7-b926-e479767bc74f' User entered 'None (0)'	System	15 Sep 2020 17:02:18
	System	15 Sep 2020 17:02:18

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-15T12:01:08', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '8c4f03ff-6b35-47b7-b926-e479767bc74f' User entered 'None (0)'	System	15 Sep 2020 17:02:18
	System	15 Sep 2020 17:02:18

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-15T12:01:10', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '8c4f03ff-6b35-47b7-b926-e479767bc74f' User entered 'None (0)'	System	15 Sep 2020 17:02:18
	System	15 Sep 2020 17:02:18

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-15T12:01:14', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '8c4f03ff-6b35-47b7-b926-e479767bc74f' User entered 'None (0)'	System	15 Sep 2020 17:02:18
	System	15 Sep 2020 17:02:18

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-15T12:01:16', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '8c4f03ff-6b35-47b7-b926-e479767bc74f' User entered 'None (0)'	System	15 Sep 2020 17:02:18
	System	15 Sep 2020 17:02:18

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-15T12:01:18', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '8c4f03ff-6b35-47b7-b926-e479767bc74f' User entered 'None (0)'	System	15 Sep 2020 17:02:18
	System	15 Sep 2020 17:02:18

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-15T12:01:22', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '8c4f03ff-6b35-47b7-b926-e479767bc74f' User entered 'No (N)'	System	15 Sep 2020 17:02:18
	System	15 Sep 2020 17:02:18

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-15T12:01:25', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '8c4f03ff-6b35-47b7-b926-e479767bc74f' User entered '15 Sep 2020 12:01'	System	15 Sep 2020 17:02:18
	System	15 Sep 2020 17:02:18

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 3'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T09:49:45', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd0364e8d-56d4-47cd-b62f-298aaf70b99e' User entered 'None (0)'	System	17 Sep 2020 14:50:19
	System	17 Sep 2020 14:50:19

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T09:49:49', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd0364e8d-56d4-47cd-b62f-298aaf70b99e' User entered 'None (0)'	System	17 Sep 2020 14:50:19
	System	17 Sep 2020 14:50:19

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T09:49:55', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd0364e8d-56d4-47cd-b62f-298aaf70b99e' User entered 'None (0)'	System	17 Sep 2020 14:50:19
	System	17 Sep 2020 14:50:19

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T09:49:59', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd0364e8d-56d4-47cd-b62f-298aaf70b99e' User entered 'None (0)'	System	17 Sep 2020 14:50:19
	System	17 Sep 2020 14:50:19

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T09:50:03', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd0364e8d-56d4-47cd-b62f-298aaf70b99e' User entered 'None (0)'	System	17 Sep 2020 14:50:19
	System	17 Sep 2020 14:50:19

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T09:50:05', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd0364e8d-56d4-47cd-b62f-298aaf70b99e' User entered 'None (0)'	System	17 Sep 2020 14:50:19
	System	17 Sep 2020 14:50:19

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T09:50:14', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd0364e8d-56d4-47cd-b62f-298aaf70b99e' User entered 'No (N)'	System	17 Sep 2020 14:50:19
	System	17 Sep 2020 14:50:19

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T09:50:16', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd0364e8d-56d4-47cd-b62f-298aaf70b99e' User entered '17 Sep 2020 09:50'	System	17 Sep 2020 14:50:19
	System	17 Sep 2020 14:50:19

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 4'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T12:01:54', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e7fd8164-ba43-4f85-9632-fc97a49fc364' User entered 'None (0)'	System	17 Sep 2020 17:03:22
	System	17 Sep 2020 17:03:22

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T12:01:56', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e7fd8164-ba43-4f85-9632-fc97a49fc364' User entered 'None (0)'	System	17 Sep 2020 17:03:22
	System	17 Sep 2020 17:03:22

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T12:01:58', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e7fd8164-ba43-4f85-9632-fc97a49fc364' User entered 'None (0)'	System	17 Sep 2020 17:03:22
	System	17 Sep 2020 17:03:22

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T12:02:01', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e7fd8164-ba43-4f85-9632-fc97a49fc364' User entered 'None (0)'	System	17 Sep 2020 17:03:22
	System	17 Sep 2020 17:03:22

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T12:02:03', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e7fd8164-ba43-4f85-9632-fc97a49fc364' User entered 'None (0)'	System	17 Sep 2020 17:03:22
	System	17 Sep 2020 17:03:22

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T12:02:08', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e7fd8164-ba43-4f85-9632-fc97a49fc364' User entered 'None (0)'	System	17 Sep 2020 17:03:22
	System	17 Sep 2020 17:03:22

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T12:02:11', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e7fd8164-ba43-4f85-9632-fc97a49fc364'	System	17 Sep 2020 17:03:22
User entered 'No (N)'	System	17 Sep 2020 17:03:22

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-17T12:02:14', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e7fd8164-ba43-4f85-9632-fc97a49fc364' User entered '17 Sep 2020 12:02'	System	17 Sep 2020 17:03:22
	System	17 Sep 2020 17:03:22

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 5'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T07:16:29', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '42dca37d-ee69-46db-a6b3-ae534013c685' User entered 'None (0)'	System	19 Sep 2020 12:16:46
	System	19 Sep 2020 12:16:46

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T07:16:31', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '42dca37d-ee69-46db-a6b3-ae534013c685' User entered 'None (0)'	System	19 Sep 2020 12:16:46
	System	19 Sep 2020 12:16:46

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T07:16:33', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '42dca37d-ee69-46db-a6b3-ae534013c685' User entered 'None (0)'	System	19 Sep 2020 12:16:46
	System	19 Sep 2020 12:16:46

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T07:16:34', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '42dca37d-ee69-46db-a6b3-ae534013c685' User entered 'None (0)'	System	19 Sep 2020 12:16:46
	System	19 Sep 2020 12:16:46

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T07:16:36', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '42dca37d-ee69-46db-a6b3-ae534013c685' User entered 'None (0)'	System	19 Sep 2020 12:16:46
	System	19 Sep 2020 12:16:46

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T07:16:38', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '42dca37d-ee69-46db-a6b3-ae534013c685' User entered 'None (0)'	System	19 Sep 2020 12:16:46
	System	19 Sep 2020 12:16:46

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T07:16:41', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '42dca37d-ee69-46db-a6b3-ae534013c685' User entered 'No (N)'	System	19 Sep 2020 12:16:46
	System	19 Sep 2020 12:16:46

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T07:16:43', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '42dca37d-ee69-46db-a6b3-ae534013c685' User entered '19 Sep 2020 07:16'	System	19 Sep 2020 12:16:46
	System	19 Sep 2020 12:16:46

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 6'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T12:01:54', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '4658798a-bc09-419b-a74e-5515d4fc1a0a' User entered 'None (0)'	System	19 Sep 2020 17:02:42
	System	19 Sep 2020 17:02:42

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T12:01:56', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '4658798a-bc09-419b-a74e-5515d4fc1a0a' User entered 'None (0)'	System	19 Sep 2020 17:02:42
	System	19 Sep 2020 17:02:42

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T12:01:59', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '4658798a-bc09-419b-a74e-5515d4fc1a0a' User entered 'None (0)'	System	19 Sep 2020 17:02:42
	System	19 Sep 2020 17:02:42

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T12:02:02', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '4658798a-bc09-419b-a74e-5515d4fc1a0a' User entered 'None (0)'	System	19 Sep 2020 17:02:42
	System	19 Sep 2020 17:02:42

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T12:02:04', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '4658798a-bc09-419b-a74e-5515d4fc1a0a' User entered 'None (0)'	System	19 Sep 2020 17:02:42
	System	19 Sep 2020 17:02:42

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T12:02:06', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '4658798a-bc09-419b-a74e-5515d4fc1a0a' User entered 'None (0)'	System	19 Sep 2020 17:02:42
	System	19 Sep 2020 17:02:42

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T12:02:09', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '4658798a-bc09-419b-a74e-5515d4fc1a0a' User entered 'No (N)'	System	19 Sep 2020 17:02:42
	System	19 Sep 2020 17:02:42

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-19T12:02:12', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '4658798a-bc09-419b-a74e-5515d4fc1a0a' User entered '19 Sep 2020 12:02'	System	19 Sep 2020 17:02:42
	System	19 Sep 2020 17:02:42

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	14 Sep 2020 16:26:51
User entered 'Day 7'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-20T12:01:22', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'f9e330c6-e5c5-4184-98a5-31f2b94da9c0'	System	20 Sep 2020 17:01:56
User entered 'None (0)'	System	20 Sep 2020 17:01:56

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-20T12:01:25', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'f9e330c6-e5c5-4184-98a5-31f2b94da9c0' User entered 'None (0)'	System	20 Sep 2020 17:01:56
	System	20 Sep 2020 17:01:56

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-20T12:01:27', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'f9e330c6-e5c5-4184-98a5-31f2b94da9c0' User entered 'None (0)'	System	20 Sep 2020 17:01:56
	System	20 Sep 2020 17:01:56

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-20T12:01:30', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'f9e330c6-e5c5-4184-98a5-31f2b94da9c0' User entered 'None (0)'	System	20 Sep 2020 17:01:56
	System	20 Sep 2020 17:01:56

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-20T12:01:33', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'f9e330c6-e5c5-4184-98a5-31f2b94da9c0' User entered 'None (0)'	System	20 Sep 2020 17:01:56
	System	20 Sep 2020 17:01:56

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-20T12:01:35', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'f9e330c6-e5c5-4184-98a5-31f2b94da9c0' User entered 'None (0)'	System	20 Sep 2020 17:01:56
	System	20 Sep 2020 17:01:56

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-20T12:01:38', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'f9e330c6-e5c5-4184-98a5-31f2b94da9c0' User entered 'No (N)'	System	20 Sep 2020 17:01:56
	System	20 Sep 2020 17:01:56

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-09-20T12:01:41', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'f9e330c6-e5c5-4184-98a5-31f2b94da9c0' User entered '20 Sep 2020 12:01'	System	20 Sep 2020 17:01:56
	System	20 Sep 2020 17:01:56

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:26:51

US3392049

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:26:51

US3392049

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:52:24
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	21 Sep 2020 19:56:45

US3392049

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:52:24
User entered '21 Sep 2020'	(b) (4) Brandon Illickal (b) (4)	21 Sep 2020 19:56:45

US3392049

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 01:52:24
User entered 'Contact Made (CONTACT MADE)'	Brandon Illickal (b) (4) (b) (4)	21 Sep 2020 19:56:45

US3392049

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:52:24
User entered empty.	(b) (4) Brandon Illickal (b) (4)	21 Sep 2020 19:56:45

US3392049

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:52:24
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	21 Sep 2020 19:56:58

US3392049

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered '1'	System	21 Sep 2020 19:56:58

US3392049

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:35:39
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 18:57:52

US3392049

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:35:39
User entered '28 Sep 2020'	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 18:57:52

US3392049

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 01:35:39
User entered 'Contact Made (CONTACT MADE)'	Brandon Illickal (b) (4) (b) (4)	28 Sep 2020 18:57:52

US3392049

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:35:39
User entered empty.	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 18:57:52

US3392049

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:35:39
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 18:57:57

US3392049

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered '1'	System	28 Sep 2020 18:57:57

US3392049

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	20 Feb 2021 01:18:25
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	05 Oct 2020 20:01:36

US3392049

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:18:25
User entered '5 Oct 2020'	(b) (4) Brandon Illickal (b) (4)	05 Oct 2020 20:01:36

US3392049

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:18:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Brandon Illickal (b) (4)	05 Oct 2020 20:01:36

US3392049

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:18:25
User entered empty.	(b) (4) Brandon Illickal (b) (4)	05 Oct 2020 20:01:36

US3392049

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:18:25
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	05 Oct 2020 20:01:41

US3392049

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered '1'	System	05 Oct 2020 20:01:41

US3392049

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:02

US3392049

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered '9 Oct 2020'	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:02

US3392049

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered 'Clinic (Clinic)'	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:02

US3392049

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'VISIT3'	System	09 Oct 2020 15:29:02

US3392049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:08

US3392049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered empty.	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:08

US3392049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered empty.	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:08

US3392049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered empty.	System	09 Oct 2020 15:29:08

US3392049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered empty.	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:08

US3392049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered empty.	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:08

US3392049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered empty.	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:08

US3392049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered empty.	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:08

US3392049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered empty.	System	09 Oct 2020 15:29:08

US3392049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered empty.	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:08

US3392049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered empty.	System	09 Oct 2020 15:29:08

US3392049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered empty.	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:08

US3392049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered empty.	System	09 Oct 2020 15:29:08

US3392049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered empty.	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:08

US3392049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered empty.	System	09 Oct 2020 15:29:08

US3392049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18

US3392049

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18

US3392049

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:13

US3392049

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered empty.	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:13

US3392049

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:44

US3392049

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered '9 Oct 2020'	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:44

US3392049

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered '10:15'	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:44

US3392049

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered '9 Oct 2020 10:15'	System	09 Oct 2020 15:29:44

US3392049

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:18:48
User entered 'Yes (Y)'	(b) (4) Brandon Illickal (b) (4)	09 Oct 2020 15:29:49

US3392049

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered '1'	System	09 Oct 2020 15:29:49

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 64'	System	19 Aug 2020 16:04:31

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-10-19T07:52:28', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '0051869d-9440-457b-9fe9-68f417019769'	System	19 Oct 2020 12:52:48
User entered 'No (N)'	System	19 Oct 2020 12:52:48

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-10-19T07:52:36', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '0051869d-9440-457b-9fe9-68f417019769'	System	19 Oct 2020 12:52:48
User entered 'No (N)'	System	19 Oct 2020 12:52:48

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-10-19T07:52:46', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '0051869d-9440-457b-9fe9-68f417019769' User entered '19 Oct 2020 07:52:46'	System	19 Oct 2020 12:52:48
	System	19 Oct 2020 12:52:48

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 16:04:31

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 71'	System	19 Aug 2020 16:04:31

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-10-26T09:30:57', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '3aa6b9eb-3cbf-41d1-a4cb-70b201915301'	System	26 Oct 2020 14:31:08
User entered 'No (N)'	System	26 Oct 2020 14:31:08

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-10-26T09:31:01', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '3aa6b9eb-3cbf-41d1-a4cb-70b201915301'	System	26 Oct 2020 14:31:08
User entered 'No (N)'	System	26 Oct 2020 14:31:08

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-10-26T09:31:05', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '3aa6b9eb-3cbf-41d1-a4cb-70b201915301' User entered '26 Oct 2020 09:31:05'	System	26 Oct 2020 14:31:08
	System	26 Oct 2020 14:31:08

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 16:04:31

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 78'	System	19 Aug 2020 16:04:31

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-11-05T17:46:13', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a2956516-5270-4cd5-9fc5-9f30a70edeb5'	System	05 Nov 2020 23:57:06
User entered 'No (N)'	System	05 Nov 2020 23:57:06

US3392049

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-11-05T17:46:23', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a2956516-5270-4cd5-9fc5-9f30a70edeb5' User entered 'Yes (Y)'	System	05 Nov 2020 23:57:06
	System	05 Nov 2020 23:57:06

US3392049

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-11-05T17:56:53', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a2956516-5270-4cd5-9fc5-9f30a70edeb5'	System	05 Nov 2020 23:57:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Nov 2020 23:57:06

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-11-05T17:56:57', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a2956516-5270-4cd5-9fc5-9f30a70edeb5' User entered '05 Nov 2020 17:56:57'	System	05 Nov 2020 23:57:06
	System	05 Nov 2020 23:57:06

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 16:04:31

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered 'Day 92'	System	19 Aug 2020 16:04:31

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-11-16T08:09:47', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'cea73b22-a76e-4a65-b3c7-786880122343' User entered 'No (N)'	System	16 Nov 2020 14:10:14
	System	16 Nov 2020 14:10:14

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-11-16T08:09:55', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'cea73b22-a76e-4a65-b3c7-786880122343' User entered 'No (N)'	System	16 Nov 2020 14:10:14
	System	16 Nov 2020 14:10:14

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-11-16T08:10:10', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'cea73b22-a76e-4a65-b3c7-786880122343' User entered '16 Nov 2020 08:10:10'	System	16 Nov 2020 14:10:14
	System	16 Nov 2020 14:10:14

US3392049

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 16:04:31

US3392049

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:20:10
Data entry locked.	System	19 Aug 2020 16:04:31
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 16:04:31

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-11-27T07:49:37', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '7b71c049-890a-4367-b3a0-e025d36e3d49'	System	27 Nov 2020 13:49:50
User entered 'No (N)'	System	27 Nov 2020 13:49:50

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-11-27T07:49:41', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '7b71c049-890a-4367-b3a0-e025d36e3d49'	System	27 Nov 2020 13:49:50
User entered 'No (N)'	System	27 Nov 2020 13:49:50

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-11-27T07:49:48', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '7b71c049-890a-4367-b3a0-e025d36e3d49'	System	27 Nov 2020 13:49:50
User entered '27 Nov 2020 07:49:48'	System	27 Nov 2020 13:49:50

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-12-04T07:21:17', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '3d967f1e-ced1-4184-8ab3-ce9eace8305a'	System	04 Dec 2020 13:21:39
User entered 'No (N)'	System	04 Dec 2020 13:21:39

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-12-04T07:21:26', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '3d967f1e-ced1-4184-8ab3-ce9eace8305a'	System	04 Dec 2020 13:21:39
User entered 'No (N)'	System	04 Dec 2020 13:21:39

US3392049

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-12-04T07:21:33', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '3d967f1e-ced1-4184-8ab3-ce9eace8305a' User entered '04 Dec 2020 07:21:33'	System	04 Dec 2020 13:21:39
	System	04 Dec 2020 13:21:39

US3392049

Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-12-11T00:02:04', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd8092996-a51d-41c1-9906-b9ec83f74fa4'	System	11 Dec 2020 06:02:24
User entered 'No (N)'	System	11 Dec 2020 06:02:24

US3392049

Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-12-11T00:02:11', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd8092996-a51d-41c1-9906-b9ec83f74fa4'	System	11 Dec 2020 06:02:24
User entered 'No (N)'	System	11 Dec 2020 06:02:24

US3392049

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-12-11T00:02:20', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd8092996-a51d-41c1-9906-b9ec83f74fa4'	System	11 Dec 2020 06:02:24
User entered '11 Dec 2020 00:02:20'	System	11 Dec 2020 06:02:24

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-12-18T08:00:36', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'f71efda4-af50-4299-b2a8-564e44df2ff8'	System	18 Dec 2020 14:01:02
User entered 'No (N)'	System	18 Dec 2020 14:01:02

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-12-18T08:00:45', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'f71efda4-af50-4299-b2a8-564e44df2ff8'	System	18 Dec 2020 14:01:02
User entered 'No (N)'	System	18 Dec 2020 14:01:02

US3392049

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-12-18T08:00:57', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'f71efda4-af50-4299-b2a8-564e44df2ff8' User entered '18 Dec 2020 08:00:57'	System	18 Dec 2020 14:01:02
	System	18 Dec 2020 14:01:02

US3392049

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-12-28T19:10:18', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '7076edff-7dfe-49f8-923b-7a4823f79f3d'	System	29 Dec 2020 01:11:04
User entered 'Yes (Y)'	System	29 Dec 2020 01:11:04

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-12-28T19:10:21', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '7076edff-7dfe-49f8-923b-7a4823f79f3d'	System	29 Dec 2020 01:11:04
User entered 'No (N)'	System	29 Dec 2020 01:11:04

US3392049

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Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-12-28T19:10:30', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '7076edff-7dfe-49f8-923b-7a4823f79f3d'	System	29 Dec 2020 01:11:04
User entered 'No (N)'	System	29 Dec 2020 01:11:04

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-12-28T19:10:40', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '7076edff-7dfe-49f8-923b-7a4823f79f3d'	System	29 Dec 2020 01:11:04
User entered 'Yes (Y)'	System	29 Dec 2020 01:11:04

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-12-28T19:10:49', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '7076edff-7dfe-49f8-923b-7a4823f79f3d'	System	29 Dec 2020 01:11:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Dec 2020 01:11:04

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2020-12-28T19:10:55', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '7076edff-7dfe-49f8-923b-7a4823f79f3d'	System	29 Dec 2020 01:11:04
User entered '28 Dec 2020 19:10:55'	System	29 Dec 2020 01:11:04

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-01-03T15:17:34', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a7f868cf-7de8-4c42-a73f-51240ad6988c'	System	03 Jan 2021 21:17:45
User entered 'No (N)'	System	03 Jan 2021 21:17:45

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-01-03T15:17:39', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a7f868cf-7de8-4c42-a73f-51240ad6988c'	System	03 Jan 2021 21:17:45
User entered 'No (N)'	System	03 Jan 2021 21:17:45

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-01-03T15:17:43', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'a7f868cf-7de8-4c42-a73f-51240ad6988c'	System	03 Jan 2021 21:17:45
User entered '03 Jan 2021 15:17:43'	System	03 Jan 2021 21:17:45

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-01-10T12:01:31', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e01a1cb5-5cc6-4a1a-8752-0b8376f47656' User entered 'No (N)'	System	10 Jan 2021 18:01:50
	System	10 Jan 2021 18:01:50

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-01-10T12:01:35', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e01a1cb5-5cc6-4a1a-8752-0b8376f47656' User entered 'No (N)'	System	10 Jan 2021 18:01:50
	System	10 Jan 2021 18:01:50

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-01-10T12:01:38', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e01a1cb5-5cc6-4a1a-8752-0b8376f47656' User entered '10 Jan 2021 12:01:38'	System	10 Jan 2021 18:01:50
	System	10 Jan 2021 18:01:50

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-01-15T08:07:10', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e4e2047c-5af3-4ee1-ab50-6d7351f2927e'	System	15 Jan 2021 14:07:23
User entered 'No (N)'	System	15 Jan 2021 14:07:23

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-01-15T08:07:17', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e4e2047c-5af3-4ee1-ab50-6d7351f2927e'	System	15 Jan 2021 14:07:23
User entered 'No (N)'	System	15 Jan 2021 14:07:23

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-01-15T08:07:21', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'e4e2047c-5af3-4ee1-ab50-6d7351f2927e' User entered '15 Jan 2021 08:07:21'	System	15 Jan 2021 14:07:23

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-01-24T12:44:43', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '30cb1c7b-eb9c-4455-a4fa-49d669e8cfa9' User entered 'No (N)'	System	24 Jan 2021 18:44:59
	System	24 Jan 2021 18:44:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-01-24T12:44:50', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '30cb1c7b-eb9c-4455-a4fa-49d669e8cfa9'	System	24 Jan 2021 18:44:59
User entered 'No (N)'	System	24 Jan 2021 18:44:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-01-24T12:44:55', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '30cb1c7b-eb9c-4455-a4fa-49d669e8cfa9' User entered '24 Jan 2021 12:44:55'	System	24 Jan 2021 18:44:59
	System	24 Jan 2021 18:44:59

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-01-29T08:25:55', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '487d3a2e-42dd-452a-a1c1-332fee30e6f3'	System	29 Jan 2021 14:26:10
User entered 'No (N)'	System	29 Jan 2021 14:26:10

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-01-29T08:26:05', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '487d3a2e-42dd-452a-a1c1-332fee30e6f3'	System	29 Jan 2021 14:26:10
User entered 'No (N)'	System	29 Jan 2021 14:26:10

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-01-29T08:26:08', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '487d3a2e-42dd-452a-a1c1-332fee30e6f3'	System	29 Jan 2021 14:26:10
User entered '29 Jan 2021 08:26:08'	System	29 Jan 2021 14:26:10

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-02-05T06:56:13', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'afe5624d-84d1-4642-a0d1-928428ff5377'	System	05 Feb 2021 12:56:27
User entered 'No (N)'	System	05 Feb 2021 12:56:27

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-02-05T06:56:20', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'afe5624d-84d1-4642-a0d1-928428ff5377'	System	05 Feb 2021 12:56:27
User entered 'No (N)'	System	05 Feb 2021 12:56:27

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-02-05T06:56:24', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'afe5624d-84d1-4642-a0d1-928428ff5377'	System	05 Feb 2021 12:56:27
User entered '05 Feb 2021 06:56:24'	System	05 Feb 2021 12:56:27

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-02-12T06:57:29', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '1faa9792-3d94-493f-9bf3-28058eb4e41c'	System	12 Feb 2021 12:57:36
User entered 'No (N)'	System	12 Feb 2021 12:57:36

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-02-12T06:57:31', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '1faa9792-3d94-493f-9bf3-28058eb4e41c'	System	12 Feb 2021 12:57:36
User entered 'No (N)'	System	12 Feb 2021 12:57:36

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-02-12T06:57:34', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '1faa9792-3d94-493f-9bf3-28058eb4e41c' User entered '12 Feb 2021 06:57:34'	System	12 Feb 2021 12:57:36
	System	12 Feb 2021 12:57:36

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-02-19T11:52:40', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '50020449-8f76-40ac-92f4-4c7bfe9e0763'	System	19 Feb 2021 16:53:01
User entered 'No (N)'	System	19 Feb 2021 16:53:01

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-02-19T11:52:51', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '50020449-8f76-40ac-92f4-4c7bfe9e0763'	System	19 Feb 2021 16:53:01
User entered 'No (N)'	System	19 Feb 2021 16:53:01

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-02-19T11:52:57', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '50020449-8f76-40ac-92f4-4c7bfe9e0763'	System	19 Feb 2021 16:53:01
User entered '19 Feb 2021 11:52:57'	System	19 Feb 2021 16:53:01

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-02-28T12:06:12-06:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '76914f31-b29b-4c1a-a6ae-cd7bcd93bf00'	System	28 Feb 2021 18:10:33
User entered 'No (N)'	System	28 Feb 2021 18:10:33

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-02-28T12:06:19-06:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '76914f31-b29b-4c1a-a6ae-cd7bcd93bf00'	System	28 Feb 2021 18:10:33
User entered 'Yes (Y)'	System	28 Feb 2021 18:10:33

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-02-28T12:06:31-06:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '76914f31-b29b-4c1a-a6ae-cd7bcd93bf00'	System	28 Feb 2021 18:10:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Feb 2021 18:10:33

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-02-28T12:06:36-06:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '76914f31-b29b-4c1a-a6ae-cd7bcd93bf00'	System	28 Feb 2021 18:10:33
User entered '28 Feb 2021 12:06:36'	System	28 Feb 2021 18:10:33

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-03-07T15:02:25-06:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '9255b41d-32f0-419c-a4f5-040b72361ed7'	System	07 Mar 2021 21:02:36
User entered 'No (N)'	System	07 Mar 2021 21:02:36

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-03-07T15:02:27-06:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '9255b41d-32f0-419c-a4f5-040b72361ed7'	System	07 Mar 2021 21:02:36
User entered 'No (N)'	System	07 Mar 2021 21:02:36

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-03-07T15:02:31-06:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '9255b41d-32f0-419c-a4f5-040b72361ed7' User entered '07 Mar 2021 15:02:31'	System	07 Mar 2021 21:02:36
	System	07 Mar 2021 21:02:36

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-03-12T08:27:24-06:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'f9998cb1-8f01-44a2-af9d-615157b4d657'	System	12 Mar 2021 14:27:40
User entered 'No (N)'	System	12 Mar 2021 14:27:40

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-03-12T08:27:34-06:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'f9998cb1-8f01-44a2-af9d-615157b4d657'	System	12 Mar 2021 14:27:40
User entered 'No (N)'	System	12 Mar 2021 14:27:40

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-03-12T08:27:37-06:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'f9998cb1-8f01-44a2-af9d-615157b4d657'	System	12 Mar 2021 14:27:40
User entered '12 Mar 2021 08:27:37'	System	12 Mar 2021 14:27:40

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-03-20T09:14:24-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd8a1aaf1-dee3-4eb1-8ea8-6a0432a7e1b8'	System	20 Mar 2021 14:14:32
User entered 'No (N)'	System	20 Mar 2021 14:14:32

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-03-20T09:14:27-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd8a1aaf1-dee3-4eb1-8ea8-6a0432a7e1b8'	System	20 Mar 2021 14:14:32
User entered 'No (N)'	System	20 Mar 2021 14:14:32

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-03-20T09:14:30-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'd8a1aaf1-dee3-4eb1-8ea8-6a0432a7e1b8'	System	20 Mar 2021 14:14:32
User entered '20 Mar 2021 09:14:30'	System	20 Mar 2021 14:14:32

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-03-28T12:00:40-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'ead6f008-a0ca-4b32-a52d-81560fca211b'	System	28 Mar 2021 17:01:10
User entered 'No (N)'	System	28 Mar 2021 17:01:10

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-03-28T12:00:44-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'ead6f008-a0ca-4b32-a52d-81560fca211b'	System	28 Mar 2021 17:01:10
User entered 'No (N)'	System	28 Mar 2021 17:01:10

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-03-28T12:00:48-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'ead6f008-a0ca-4b32-a52d-81560fca211b' User entered '28 Mar 2021 12:00:48'	System	28 Mar 2021 17:01:10
	System	28 Mar 2021 17:01:10

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-04-03T10:10:24-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '273f87a4-7479-41da-9ca2-fcb7e49e4601'	System	03 Apr 2021 15:10:31
User entered 'No (N)'	System	03 Apr 2021 15:10:31

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-04-03T10:10:26-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '273f87a4-7479-41da-9ca2-fcb7e49e4601'	System	03 Apr 2021 15:10:31
User entered 'No (N)'	System	03 Apr 2021 15:10:31

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-04-03T10:10:29-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '273f87a4-7479-41da-9ca2-fcb7e49e4601'	System	03 Apr 2021 15:10:31
User entered '03 Apr 2021 10:10:29'	System	03 Apr 2021 15:10:31

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-04-09T08:13:58-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '5294b601-a37a-488f-a412-159b12e35e03'	System	09 Apr 2021 13:14:12
User entered 'No (N)'	System	09 Apr 2021 13:14:12

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-04-09T08:14:06-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '5294b601-a37a-488f-a412-159b12e35e03'	System	09 Apr 2021 13:14:12
User entered 'No (N)'	System	09 Apr 2021 13:14:12

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-04-09T08:14:10-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '5294b601-a37a-488f-a412-159b12e35e03'	System	09 Apr 2021 13:14:12
User entered '09 Apr 2021 08:14:10'	System	09 Apr 2021 13:14:12

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-04-16T12:00:24-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '1b805955-f26b-4d84-bf90-970718578eae' User entered 'No (N)'	System	16 Apr 2021 17:00:45
	System	16 Apr 2021 17:00:45

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-04-16T12:00:26-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '1b805955-f26b-4d84-bf90-970718578eae'	System	16 Apr 2021 17:00:45
User entered 'No (N)'	System	16 Apr 2021 17:00:45

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-04-16T12:00:29-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '1b805955-f26b-4d84-bf90-970718578eae' User entered '16 Apr 2021 12:00:29'	System	16 Apr 2021 17:00:45
	System	16 Apr 2021 17:00:45

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-04-24T09:08:07-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '98aae422-54ec-4674-aeca-b552bc0dd44f'	System	24 Apr 2021 14:08:17
User entered 'No (N)'	System	24 Apr 2021 14:08:17

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-04-24T09:08:10-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '98aae422-54ec-4674-aeca-b552bc0dd44f'	System	24 Apr 2021 14:08:17
User entered 'No (N)'	System	24 Apr 2021 14:08:17

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-04-24T09:08:13-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '98aae422-54ec-4674-aeca-b552bc0dd44f'	System	24 Apr 2021 14:08:17
User entered '24 Apr 2021 09:08:13'	System	24 Apr 2021 14:08:17

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-04-30T08:59:41-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'c50a3351-4b02-4a10-9c49-151878517888'	System	30 Apr 2021 13:59:49
User entered 'No (N)'	System	30 Apr 2021 13:59:49

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-04-30T08:59:43-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'c50a3351-4b02-4a10-9c49-151878517888'	System	30 Apr 2021 13:59:49
User entered 'No (N)'	System	30 Apr 2021 13:59:49

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-04-30T08:59:46-05:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: 'c50a3351-4b02-4a10-9c49-151878517888'	System	30 Apr 2021 13:59:49
User entered '30 Apr 2021 08:59:46'	System	30 Apr 2021 13:59:49

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 22:51:58

US3392049

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:51:58
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 22:51:58

US3392049

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:22:36

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:40:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-03-01T10:13:04-06:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '4adcd953-fd48-4a9e-9ea0-c0cde51ee47f'	System	01 Mar 2021 16:13:14
User entered 'No (N)'	System	01 Mar 2021 16:13:14

US3392049

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:22:36

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:40:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F68341F8-CD95-4B60-9299-FFD7C24C3303)', Time: '2021-03-01T10:13:09-06:00', User OID: 'PatientReportedOutcome (US3392049)', ODM File OID: '4adcd953-fd48-4a9e-9ea0-c0cde51ee47f' User entered '01 Mar 2021 10:13:09'	System	01 Mar 2021 16:13:14
	System	01 Mar 2021 16:13:14

US3392049

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:52:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 23:56:58

US3392049

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:52:21
User entered '6 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 23:56:58

US3392049

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:52:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 23:56:58

US3392049

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:52:21
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 23:56:58

US3392049

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:52:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 23:56:47

US3392049

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:24:18
User entered 'I'	System	12 Nov 2020 23:56:47

US3392049

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:02:18
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	Brenda Lawson (b) (4) (b) (4)	28 Dec 2020 21:07:42

US3392049

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:02:18
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '30 Nov 2020'	Brenda Lawson (b) (4)	28 Dec 2020 21:07:42

US3392049

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:02:18
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Brenda Lawson (b) (4)	28 Dec 2020 21:07:42

US3392049

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:02:18
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	Brenda Lawson (b) (4)	28 Dec 2020 21:07:42

US3392049

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:02:18
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	28 Dec 2020 21:07:46

US3392049

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:02:18
User entered '1'	System	28 Dec 2020 21:07:46

US3392049

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:59:45
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	Brenda Lawson (b) (4) (b) (4)	01 Apr 2021 17:46:07

US3392049

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:59:45
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '11 Jan 2021'	Brenda Lawson (b) (4)	01 Apr 2021 17:46:07

US3392049

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:59:45
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Contact Made (CONTACT MADE)'	Brenda Lawson (b) (4)	01 Apr 2021 17:46:07

US3392049

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:59:45
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	Brenda Lawson (b) (4)	01 Apr 2021 17:46:07

US3392049

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:59:45
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	Brenda Lawson (b) (4) (b) (4)	08 Feb 2021 23:06:40

US3392049

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:59:45
User entered '1'	System	08 Feb 2021 23:06:40

US3392049

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:29:31
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	08 Feb 2021 23:06:58

US3392049

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:29:31
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '08 Feb 2021'	Brenda Lawson (b) (4)	08 Feb 2021 23:06:58

US3392049

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:29:31
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Brenda Lawson (b) (4)	08 Feb 2021 23:06:58

US3392049

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:29:31
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	Brenda Lawson (b) (4)	08 Feb 2021 23:06:58

US3392049

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:29:31
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	08 Feb 2021 23:07:04

US3392049

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:29:31
User entered '1'	System	08 Feb 2021 23:07:04

US3392049

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:16:59

US3392049

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:16:59

US3392049

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:16:59

US3392049

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User entered 'VISIT4'	System	01 Mar 2021 21:16:59

US3392049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	31 Mar 2021 22:07:55

US3392049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) Brandon Illickal (b) (4)	31 Mar 2021 22:07:55

US3392049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) Brandon Illickal (b) (4)	31 Mar 2021 22:07:55

US3392049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User entered empty.	System	31 Mar 2021 22:07:55

US3392049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) Brandon Illickal (b) (4)	31 Mar 2021 22:07:55

US3392049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) Brandon Illickal (b) (4)	31 Mar 2021 22:07:55

US3392049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) Brandon Illickal (b) (4)	31 Mar 2021 22:07:55

US3392049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) Brandon Illickal (b) (4)	31 Mar 2021 22:07:55

US3392049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User entered empty.	System	31 Mar 2021 22:07:55

US3392049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) Brandon Illickal (b) (4)	31 Mar 2021 22:07:55

US3392049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User entered empty.	System	31 Mar 2021 22:07:55

US3392049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) Brandon Illickal (b) (4)	31 Mar 2021 22:07:55

US3392049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User entered empty.	System	31 Mar 2021 22:07:55

US3392049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) Brandon Illickal (b) (4)	31 Mar 2021 22:07:55

US3392049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User entered empty.	System	31 Mar 2021 22:07:55

US3392049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26

US3392049

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26

US3392049

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:17:03

US3392049

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:17:03

US3392049

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:17:22

US3392049

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:17:22

US3392049

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '10:20'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:17:22

US3392049

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User entered '1 Mar 2021 10:20'	System	01 Mar 2021 21:17:22

US3392049

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:17:27

US3392049

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:13:26
User entered 'I'	System	01 Mar 2021 21:17:27

US3392049

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
	(b) (4)	
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	09 Apr 2021 18:28:24
	(b) (4)	

US3392049

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
	(b) (4)	
User entered '09 Apr 2021'	Brenda Lawson (b) (4)	09 Apr 2021 18:28:24
	(b) (4)	

US3392049

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Brenda Lawson (b) (4)	09 Apr 2021 18:28:24
	(b) (4)	

US3392049

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) Brenda Lawson (b) (4)	09 Apr 2021 18:28:24
	(b) (4)	

US3392049

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	(b) (4) Brenda Lawson (b) (4)	09 Apr 2021 18:28:37
	(b) (4)	

US3392049

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 18:28:37

US3392049

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

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:19:18

US3392049

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

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '08 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:32:51
User entered '8 Jan 2021'	(b) (4), (b) (6)	11 Jan 2021 19:19:18

US3392049

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

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:19:18

US3392049

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

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 19:19:18

US3392049

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:24
User entered '08 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:33:00
User entered '8 Jan 2021'	(b) (4), (b) (6)	11 Jan 2021 19:19:49

US3392049

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:24
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:21:39
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:44:37

US3392049

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 19:19:49

US3392049

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:24
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)	09 Apr 2021 20:50:35
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 'Updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 20:21:45
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Apr 2021 20:21:39
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 19:19:37
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:44:37

US3392049

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:24
User entered '08 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:33:00
User entered '8 Jan 2021'	(b) (4), (b) (6)	11 Jan 2021 19:19:49

US3392049

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:24
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	11 Jan 2021 19:19:49

US3392049

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:24
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 02:41:51
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	11 Jan 2021 19:19:49

US3392049

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:24
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 02:41:51
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	11 Jan 2021 19:19:49

US3392049

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 19:19:49

US3392049

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User entered '1'	System	11 Jan 2021 19:19:49

US3392049

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User entered '1'	System	11 Jan 2021 19:19:49

US3392049

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User entered '68.0' in	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User entered '180.0' lb	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User entered '27.42613'	System	11 Jan 2021 19:20:22
DataPoint set to visible.	System	11 Jan 2021 19:19:49

US3392049

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User entered '68.0' in	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User entered '180.0' lb	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User entered '27.42613'	System	11 Jan 2021 19:20:22
DataPoint set to visible.	System	11 Jan 2021 19:19:49

US3392049

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 19:21:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 19:21:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:21:02
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 19:20:22
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User entered '08 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:33:11
User entered '8 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:21:02
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User entered '10:32' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:21:02
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User entered '08 Jan 2021 10:32'	System	11 Jan 2021 19:33:11
User entered '8 Jan 2021 10:32'	System	11 Jan 2021 19:21:02
User entered empty.	System	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User entered '98.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:21:02
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:21:02
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User entered '86' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:21:02
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User entered 'bpm'	System	11 Jan 2021 19:21:02
User entered empty.	System	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:21:02
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User entered 'breaths/min'	System	11 Jan 2021 19:21:02
User entered empty.	System	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User entered '114' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:21:02
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User entered 'mmHg'	System	11 Jan 2021 19:21:02
User entered empty.	System	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User entered '79' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:21:02
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User entered 'mmHg'	System	11 Jan 2021 19:21:02
User entered empty.	System	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User entered '68.0' in	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User entered '180.0' lb	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User entered '27.42613'	System	11 Jan 2021 19:20:22
DataPoint set to visible.	System	11 Jan 2021 19:19:49

US3392049

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 19:33:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 19:33:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:33:20
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 19:20:22
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User entered '08 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:33:20
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Jan 2021 19:34:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Jan 2021 19:34:05
User entered '12:15' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:34:05
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Jan 2021 19:33:20
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User entered '08 Jan 2021 12:15'	System	11 Jan 2021 19:34:05
User entered empty.	System	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Jan 2021 19:34:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Jan 2021 19:34:05
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:34:05
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Jan 2021 19:33:20
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:34:05
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Jan 2021 19:34:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Jan 2021 19:34:05
User entered '87' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:34:05
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Jan 2021 19:33:20
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User entered 'bpm'	System	11 Jan 2021 19:34:05
User entered empty.	System	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Jan 2021 19:34:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Jan 2021 19:34:05
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:34:05
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Jan 2021 19:33:20
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User entered 'breaths/min'	System	11 Jan 2021 19:34:05
User entered empty.	System	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Jan 2021 19:34:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Jan 2021 19:34:05
User entered '145' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:34:05
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Jan 2021 19:33:20
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User entered 'mmHg'	System	11 Jan 2021 19:34:05
User entered empty.	System	11 Jan 2021 19:20:22

US3392049

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:30
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Jan 2021 19:34:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Jan 2021 19:34:05
User entered '94' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:34:05
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Jan 2021 19:33:20
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:20:22

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:03:23
User entered 'mmHg'	System	11 Jan 2021 19:34:05
User entered empty.	System	11 Jan 2021 19:20:22

US3392049

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 19:21:36

US3392049

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:51
User entered '08 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:34:18
User entered '8 Jan 2021'	(b) (4), (b) (6)	11 Jan 2021 19:21:36

US3392049

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:57
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	11 Jan 2021 19:22:20
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	11 Jan 2021 19:22:20
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	11 Jan 2021 19:22:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 19:22:08

US3392049

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:57
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:22:08

US3392049

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:57
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:22:08

US3392049

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User entered 'mRNA-1273'	System	11 Jan 2021 19:22:08
DataPoint set to visible.	System	11 Jan 2021 19:19:49

US3392049

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:57
User entered '08 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:34:26
User entered '8 Jan 2021'	(b) (4), (b) (6)	11 Jan 2021 19:22:08

US3392049

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:57
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Jan 2021 19:22:31
User entered '11:43' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:22:31
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Jan 2021 19:22:08
User entered '11:4' (non-conformant).	(b) (4), (b) (6)	11 Jan 2021 19:22:08

US3392049

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User entered '08 Jan 2021 11:43'	System	11 Jan 2021 19:34:26
User entered '8 Jan 2021 11:43'	System	11 Jan 2021 19:22:31
User entered '8 Jan 2021 11:4' (non-conformant).	System	11 Jan 2021 19:22:08

US3392049

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:58:57
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 19:22:20
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 19:22:08

US3392049

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:58:57
User entered 'ONCE'	System	11 Jan 2021 19:22:08

US3392049

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

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User entered 'INTRAMUSCULAR'	System	11 Jan 2021 19:22:08

US3392049

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:22:57

US3392049

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '08 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:34:32
User entered '8 Jan 2021'	(b) (4), (b) (6)	11 Jan 2021 19:22:57

US3392049

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '10:40'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:22:57

US3392049

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User entered '08 Jan 2021 10:40'	System	11 Jan 2021 19:34:32
User entered '8 Jan 2021 10:40'	System	11 Jan 2021 19:22:57

US3392049

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:23:10

US3392049

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:22:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '08 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:34:39
User entered '8 Jan 2021'	(b) (4), (b) (6)	11 Jan 2021 19:23:10

US3392049

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '10:42'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:23:10

US3392049

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User entered '08 Jan 2021 10:42'	System	11 Jan 2021 19:34:39
User entered '8 Jan 2021 10:42'	System	11 Jan 2021 19:23:10

US3392049

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

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:23:15

US3392049

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

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:02:44
User entered '1'	System	11 Jan 2021 19:23:15

US3392049

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:19:30
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	Heather Salisbury (b) (4) (b) (4)	18 Jan 2021 18:17:55

US3392049

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:19:30
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '18 Jan 2021'	Heather Salisbury (b) (4)	18 Jan 2021 18:17:55

US3392049

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:19:30
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Contact Made (CONTACT MADE)'	Heather Salisbury (b) (4)	18 Jan 2021 18:17:55

US3392049

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:19:30
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) Heather Salisbury (b) (4)	18 Jan 2021 18:17:55
	(b) (4)	

US3392049

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:19:30
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	18 Jan 2021 18:17:58

US3392049

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:19:30
User entered '1'	System	18 Jan 2021 18:17:58

US3392049

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:19:30
User entered '1'	System	18 Jan 2021 18:17:58
DataPoint set to visible.	System	18 Jan 2021 18:17:58

US3392049

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:25:29

US3392049

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:25:29

US3392049

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:25:29

US3392049

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User entered 'OLD29'	System	02 Feb 2021 19:25:29

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '09:45'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User entered '2 Feb 2021 09:45'	System	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '90'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User entered 'bpm'	System	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '14'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User entered 'breaths/min'	System	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '106'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User entered 'mmHg'	System	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '66'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User entered 'mmHg'	System	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '10:48'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User entered '2 Feb 2021 10:48'	System	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '97'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User entered 'bpm'	System	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '16'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User entered 'breaths/min'	System	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '113'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User entered 'mmHg'	System	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '77'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User entered 'mmHg'	System	02 Feb 2021 19:26:37

US3392049

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:46

US3392049

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:26:46

US3392049

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:27:55

US3392049

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:27:55

US3392049

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:27:55

US3392049

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User entered 'mRNA-1273'	System	02 Feb 2021 19:27:55
DataPoint set to visible.	System	18 Jan 2021 18:17:58

US3392049

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:27:55

US3392049

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '10:09'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:27:55

US3392049

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User entered '2 Feb 2021 10:09'	System	02 Feb 2021 19:27:55

US3392049

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:27:55

US3392049

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User entered 'ONCE'	System	02 Feb 2021 19:27:55

US3392049

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User entered 'INTRAMUSCULAR'	System	02 Feb 2021 19:27:55

US3392049

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:25:19

US3392049

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:08
User entered '1'	System	02 Feb 2021 19:25:19

US3392049

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:56:02
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:17:44

US3392049

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:56:02
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:17:44

US3392049

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:56:02
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:17:44

US3392049

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:56:02
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:17:44

US3392049

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:56:02
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:17:48

US3392049

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:56:02
User entered 'I'	System	01 Mar 2021 21:17:48

US3392049

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:18:01

US3392049

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:18:01

US3392049

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:18:01

US3392049

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User entered 'OLD57'	System	01 Mar 2021 21:18:01

US3392049

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:18:07

US3392049

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:18:07

US3392049

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:18:07

US3392049

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User entered empty.	System	01 Mar 2021 21:18:07

US3392049

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:18:07

US3392049

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:18:07

US3392049

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:18:07

US3392049

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:18:07

US3392049

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User entered empty.	System	01 Mar 2021 21:18:07

US3392049

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:18:07

US3392049

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User entered empty.	System	01 Mar 2021 21:18:07

US3392049

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:18:07

US3392049

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User entered empty.	System	01 Mar 2021 21:18:07

US3392049

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:18:07

US3392049

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User entered empty.	System	01 Mar 2021 21:18:07

US3392049

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17

US3392049

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17

US3392049

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:18:21

US3392049

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:18:21

US3392049

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:18:32

US3392049

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:18:32

US3392049

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:14:45
User entered '10:20'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:18:32

US3392049

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:22:17
User entered '1 Mar 2021 10:20'	System	01 Mar 2021 21:18:32

US3392049

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:22:36

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:25:16
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:24
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	28 Dec 2020 15:59:09

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:17:53
User entered 'USA-US119-2020-mRNA-1273-P301000013'	System	29 Dec 2020 15:17:48
User entered 'New'	(b) (4), (b) (6)	29 Dec 2020 15:17:48

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Acute myocardial infarction - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Dec 2020 16:08:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Dec 2020 16:08:20
Data point term sent to Coder	System	28 Dec 2020 16:07:17
User entered 'Acute myocardial infarction'	Brandon Illickal (b) (4) [Redacted] [Redacted]	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered 'No (N)'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered 'No (N)'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered '21 Dec 2020'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered empty.	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered 'No (N)'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered '23 Dec 2020'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered empty.	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered 'Grade 3/Severe (Grade 3/Severe)'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	28 Dec 2020 16:07:03
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	28 Dec 2020 16:06:27
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered '0'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered '0'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		28 Dec 2020 16:07:03
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		28 Dec 2020 16:07:03
User entered '1' reason for change: Data Entry Error	Brandon Illickal (b) (4)	28 Dec 2020 16:07:03
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	28 Dec 2020 16:06:27
User entered '0'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered '21 Dec 2020'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered '23 Dec 2020'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered 'No (N)'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered empty.	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered '0'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered '0'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered '0'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered 'Not Applicable (NOT APPLICABLE)'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered '0'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User closed query 'PV Query: Kindly provide list of subject's concomitant medications for managing multiple underlying conditions.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 19:26:37
Query 'PV Query: Kindly provide list of subject's concomitant medications for managing multiple underlying conditions.' answered with 'DATA UPDATED.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 00:12:41
User opened query 'PV Query: Kindly provide list of subject's concomitant medications for managing multiple underlying conditions.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 20:24:12
User entered '0'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE during this time frame. Please update to record the treatment procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:20:42
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE during this time frame. Please update to record the treatment procedure as appropriate. Otherwise, clarify.' answered with 'Added two ConProc to eCRF ConProc .' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 19:29:21
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE during this time frame. Please update to record the treatment procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 07:47:15
User entered '1'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User entered empty.	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:05:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:33
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. EKG, echo, heart cath, etc.) . Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 13:44:53
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 13:44:45
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. EKG, echo, heart cath, etc.) . Please include units and reference ranges if applicable.' answered with 'All hospital records have been sent to Moderna' (Site from Safety).	Brandon Illickal (b) (4)	29 Mar 2021 16:37:49
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'hospital records with covid test results have been submitted to Moderna.' (Site from Safety).	Brandon Illickal (b) (4)	29 Mar 2021 16:37:30
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. EKG, echo, heart cath, etc.) . Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 14:06:47
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 14:06:37
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 19:26:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. EKG, echo, heart cath, etc.) . Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 19:26:33
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 19:26:31
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with '(SITE HAS NOT RECEIVED MEDICAL RECORDS RELATED TO THE SADVERSE EVENT TO THIS CURRENT DATE & TIME).SITE IS WAITING TO RECEIVE MEDICAL RECORDS RELATED TO THE ADVERSE EVENT.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 00:12:56
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. EKG, echo, heart cath, etc.) . Please include units and reference ranges if applicable.' answered with '(SITE HAS NOT RECEIVED MEDICAL RECORDS RELATED TO THE SADVERSE EVENT TO THIS CURRENT DATE & TIME).SITE IS WAITING TO RECEIVE MEDICAL RECORDS RELATED TO THE ADVERSE EVENT.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 00:12:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with '(SITE HAS NOT RECEIVED MEDICAL RECORDS RELATED TO THE SADVERSE EVENT TO THIS CURRENT DATE & TIME).SITE IS WAITING TO RECEIVE MEDICAL RECORDS RELATED TO THE ADVERSE EVENT.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 00:12:49
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 20:23:54
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e. EKG, echo, heart cath, etc.) . Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 20:23:45
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 20:23:37
User entered 'subject was admitted to hospital for acute myocardial infarction. will update once hospital records are received.'	Brandon Illickal (b) (4)	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 16:06:27

US3392049

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Dec 2020 16:06:27

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:22:36

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:25:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:36:27
User entered 'No (N)'	Brandon Illickal (b) (4)	28 Aug 2020 13:22:54

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Jan 2021 23:38:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 23:38:31
Data point term sent to Coder	System	06 Jan 2021 23:37:54
User entered 'ZOLPIDEM'	(b) (4), (b) (6)	06 Jan 2021 23:37:07

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:07

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'INSOMNIA'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:07

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '10'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:07

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:07

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:07

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:07

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:07

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:07

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:07

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'UN Jun 2018'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:07

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:07

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:07

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:07

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:07

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:37:07

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:37:07

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Jan 2021 23:37:07

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: INDOMETACIN, PRODUCTSYNONYM: INDOMETHACIN [INDOMETACIN] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Jan 2021 23:47:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 23:47:32
Data point term sent to Coder	System	06 Jan 2021 23:37:54
User entered 'INDOMETHACIN'	(b) (4), (b) (6)	06 Jan 2021 23:37:53

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:53

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'GOUT, UNSPECIFIED'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:53

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '50'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:53

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:53

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:53

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:53

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:53

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:53

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:53

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'UN Jun 2004'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:53

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:53

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:53

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:53

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:37:53

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:37:53

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:37:53

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Jan 2021 23:37:53

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Jan 2021 23:46:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 23:46:32
Data point term sent to Coder	System	06 Jan 2021 23:38:55
User entered 'ALLOPURINOL'	(b) (4), (b) (6)	06 Jan 2021 23:38:45

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:38:45

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'GOUT, UNSPECIFIED'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:38:45

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '100'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:38:45

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:38:45

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:38:45

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:38:45

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:38:45

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:38:45

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:38:45

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'UN Jan 2019'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:38:45

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:38:45

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:38:45

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:38:45

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:38:45

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 23:38:45

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 23:38:45

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 23:38:45

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Jan 2021 23:40:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 23:40:35
Data point term sent to Coder	System	06 Jan 2021 23:39:55
User entered 'METOPROLOL'	(b) (4), (b) (6)	06 Jan 2021 23:39:30

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:39:30

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:03:41
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'Med history updated' (Site from DM).	Brandon Illickal (b) (4)	25 Feb 2021 00:52:00
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 11:21:45
User entered 'HYPERTENSION'	(b) (4), (b) (6)	06 Jan 2021 23:39:30

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '50'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:39:30

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:39:30

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:39:30

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:39:30

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:39:30

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:39:30

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:39:30

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'UN May 1997'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:39:30

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:39:30

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:39:30

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:39:30

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:39:30

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:39:30

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:39:30

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Jan 2021 23:39:30

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Jan 2021 23:41:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 23:41:31
Data point term sent to Coder	System	06 Jan 2021 23:40:56
User entered 'ALPRAZOLAM'	(b) (4), (b) (6)	06 Jan 2021 23:40:14

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:14

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'INSOMNIA'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:14

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '0.25'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:14

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:14

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:14

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:14

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:14

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:14

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:14

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'UN Jun 2018'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:14

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:14

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:14

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:14

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:14

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:40:14

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:40:14

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Jan 2021 23:40:14

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	06 Jan 2021 23:43:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 23:43:32
Data point term sent to Coder	System	06 Jan 2021 23:41:57
User entered 'TAMSULOSIN'	(b) (4), (b) (6)	06 Jan 2021 23:40:59

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:59

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'ENLARGED PROSTATE'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:59

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '0.4'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:59

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:59

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:59

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:59

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:59

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:59

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:59

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:59

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:40:59

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:51:45
User entered 'No (N)'	(b) (4), (b) (6)	06 Jan 2021 23:40:59

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:51:45
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	06 Jan 2021 23:40:59
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 23:40:59

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User closed query 'Per CDM: Please confirm this medication was taken for a solicited event. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 19:37:38
Query 'Per CDM: Please confirm this medication was taken for a solicited event. Thank you' answered with 'data entry error' (Site from DM).	Brandon Illickal (b) (4)	15 Jan 2021 01:25:19
User entered 'No (N)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	15 Jan 2021 01:25:12
User opened query 'Per CDM: Please confirm this medication was taken for a solicited event. Thank you' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 15:26:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 23:40:59

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:40:59

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:40:59

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Jan 2021 23:40:59

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Jan 2021 23:46:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 23:46:32
Data point term sent to Coder	System	06 Jan 2021 23:41:57
User entered 'CELECOXIB'	(b) (4), (b) (6)	06 Jan 2021 23:41:40

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:41:40

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 14:28:21
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 16:50:05
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 11:20:34
User entered 'ARTHRITIS, LEFT FOOT'	(b) (4), (b) (6)	06 Jan 2021 23:41:40

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '200'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:41:40

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:41:40

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:41:40

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:41:40

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:41:40

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:41:40

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:41:40

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'UN May 2018'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:41:40

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:41:40

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:41:40

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:41:40

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:41:40

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:41:40

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:41:40

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Jan 2021 23:41:40

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Jan 2021 23:43:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 23:43:33
Data point term sent to Coder	System	06 Jan 2021 23:42:57
User entered 'ROSUVASTATIN'	(b) (4), (b) (6)	06 Jan 2021 23:42:12

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:12

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'HYPERCHOLESTEROLEMIA'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:12

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '40'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:12

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:12

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:12

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:12

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:12

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:12

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:12

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'UN Mar 1997'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:12

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:12

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:12

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:12

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:12

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:42:12

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:42:12

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Jan 2021 23:42:12

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Jan 2021 23:43:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 23:43:33
Data point term sent to Coder	System	06 Jan 2021 23:42:58
User entered 'ESOMEPRAZOLE'	(b) (4), (b) (6)	06 Jan 2021 23:42:56

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:56

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 14:29:08
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updating' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 16:50:41
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 11:21:04
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	(b) (4), (b) (6)	06 Jan 2021 23:42:56

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '20'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:56

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:56

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:56

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:56

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:56

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:56

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:56

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'UN Mar 2016'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:56

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:56

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:56

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:56

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:42:56

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:42:56

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:42:56

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Jan 2021 23:42:56

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EVOLOCUMAB, PRODUCTSYNONYM: REPATHA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Jan 2021 15:03:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Jan 2021 15:03:40
Data point term sent to Coder	System	06 Jan 2021 23:57:00
User entered 'REPATHA PUSHTRONEX'	(b) (4), (b) (6)	06 Jan 2021 23:56:57

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:56:57

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'HYPERCHOLESTEROLEMIA'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:56:57

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '420-3.5'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:56:57

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:56:57

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'MG-ML'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:56:57

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:56:57

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:56:57

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:56:57

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:56:57

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'UN Jun 2018'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:56:57

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:56:57

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:56:57

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:56:57

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:56:57

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:56:57

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:56:57

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Jan 2021 23:56:57

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CITRATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	15 Jan 2021 09:54:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 09:54:49
Data point term sent to Coder Coding entries removed.	System Brandon Illickal (b) (4)	15 Jan 2021 01:31:52 15 Jan 2021 01:31:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CITRATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 23:59:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 23:59:32
Data point term sent to Coder User entered 'POTASSIUM CITRATE'	System (b) (4), (b) (6)	06 Jan 2021 23:59:01 06 Jan 2021 23:58:29

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User closed query 'Per CDM: Per CCGs pg 49, prophylaxis applies to any medication used for prevention. Please reconcile, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 19:36:41
Query 'Per CDM: Per CCGs pg 49, prophylaxis applies to any medication used for prevention. Please reconcile, thank you. ' answered with 'indication updated' (Site from DM).	Brandon Illickal (b) (4)	15 Jan 2021 01:31:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	15 Jan 2021 01:31:38
User opened query 'Per CDM: Per CCGs pg 49, prophylaxis applies to any medication used for prevention. Please reconcile, thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 13:53:02
User entered 'No (N)'	(b) (4), (b) (6)	06 Jan 2021 23:58:29

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
	(b) (4)	
User entered 'worsening coronary artery disease' reason for change: Data Entry Error	Brandon Illickal (b) (4)	15 Jan 2021 01:31:38
User entered 'DIETARY SUPPLEMENT'	(b) (4), (b) (6)	06 Jan 2021 23:58:29

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '15'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:29

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:29

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'mEq'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:29

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:29

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:29

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:29

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:29

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'un Jun 2017'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:29

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:29

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:29

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:29

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:29

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:58:29

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:58:29

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Jan 2021 23:58:29

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Jan 2021 09:35:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Jan 2021 09:35:48
Data point term sent to Coder	System	15 Jan 2021 01:31:52
Coding entries removed.	Brandon Illickal (b) (4)	15 Jan 2021 01:31:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Jan 2021 00:00:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Jan 2021 00:00:32
Data point term sent to Coder	System	07 Jan 2021 00:00:03
User entered 'folic acid'	(b) (4), (b) (6)	06 Jan 2021 23:59:39

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User closed query 'Per CDM: Per CCGs pg 49, prophylaxis applies to any medication used for prevention. Please reconcile, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 19:36:52
Query 'Per CDM: Per CCGs pg 49, prophylaxis applies to any medication used for prevention. Please reconcile, thank you. ' answered with 'indication updated' (Site from DM).	Brandon Illickal (b) (4)	15 Jan 2021 01:31:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	15 Jan 2021 01:31:07
User opened query 'Per CDM: Per CCGs pg 49, prophylaxis applies to any medication used for prevention. Please reconcile, thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 13:53:18
User entered 'No (N)'	(b) (4), (b) (6)	06 Jan 2021 23:59:39

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
	(b) (4)	
User entered 'worsening CORONARY ARTERY DISEASE' reason for change: Data Entry Error	Brandon Illickal (b) (4)	15 Jan 2021 01:31:07
User entered 'CORONARY ARTERY DISEASE'	(b) (4), (b) (6)	06 Jan 2021 23:59:39

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '1'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:59:39

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:59:39

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:59:39

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:59:39

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:59:39

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:59:39

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:59:39

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'UN May 1997'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:59:39

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:59:39

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:59:39

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:59:39

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:59:39

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:59:39

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 23:59:39

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Jan 2021 23:59:39

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: OMEGA-3 FATTY ACIDS - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Jan 2021 14:54:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 14:54:52
Data point term sent to Coder	System	15 Jan 2021 01:32:52
Data point term sent to Coder	System	15 Jan 2021 01:29:51
Coding entries removed.	Brandon Illickal (b) (4)	15 Jan 2021 01:29:42
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL, PRODUCTSYNONYM: OMEGA 3 [FISH OIL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Jan 2021 14:48:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Jan 2021 14:48:40
Data point term sent to Coder	System	07 Jan 2021 00:03:05
User entered 'FISH OIL [OMEGA-3 FATTY ACIDS]'	(b) (4), (b) (6)	07 Jan 2021 00:02:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User closed query 'Per CDM: Per CCGs pg 49, prophylaxis applies to any medication used for prevention. Please reconcile, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 19:36:57
Query 'Per CDM: Per CCGs pg 49, prophylaxis applies to any medication used for prevention. Please reconcile, thank you. ' answered with 'indication updated' (Site from DM).	Brandon Illickal (b) (4)	15 Jan 2021 01:30:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	15 Jan 2021 01:29:51
User opened query 'Per CDM: Per CCGs pg 49, prophylaxis applies to any medication used for prevention. Please reconcile, thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 13:53:27
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 00:08:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Jan 2021 00:08:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 00:08:48
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 00:02:25
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 00:02:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'WORSENING coronary arteryDISEASE' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	15 Jan 2021 01:32:16
User entered 'worsening cardiovascular disease' reason for change: Data Entry Error	Brandon Illickal (b) (4)	15 Jan 2021 01:29:42
User entered 'DIETARY SUPPLEMANT'	(b) (4), (b) (6)	07 Jan 2021 00:02:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '300-1000'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'UN May 1997'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Jan 2021 00:02:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Jan 2021 00:02:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Jan 2021 00:02:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
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)	15 Jan 2021 01:46:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 01:46:59
Data point term sent to Coder	System	15 Jan 2021 01:32:53
Data point term sent to Coder	System	15 Jan 2021 01:28:51
Data point term sent to Coder	System	15 Jan 2021 01:27:50
Coding entries removed.	Brandon Illickal (b) (4)	15 Jan 2021 01:27:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: COMBINATIONS OF VITAMINS, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Jan 2021 15:00:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Jan 2021 15:00:42
Data point term sent to Coder	System	07 Jan 2021 00:11:08
User entered 'MULTIVITAMIN'	(b) (4), (b) (6)	07 Jan 2021 00:10:37

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User closed query 'Per CDM: Per CCGs pg 49, prophylaxis applies to any medication used for prevention. Please reconcile, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 19:37:05
Query 'Per CDM: Per CCGs pg 49, prophylaxis applies to any medication used for prevention. Please reconcile, thank you. ' answered with 'subject takes medication to prevent worsening cardiovascular disease.' (Site from DM).	Brandon Illickal (b) (4)	15 Jan 2021 01:27:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	15 Jan 2021 01:26:34
User opened query 'Per CDM: Per CCGs pg 49, prophylaxis applies to any medication used for prevention. Please reconcile, thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 13:53:39
User entered 'No (N)'	(b) (4), (b) (6)	07 Jan 2021 00:10:37

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
	(b) (4)	
User entered 'WORSENING coronary artery DISEASE' reason for change: Data Entry Error	Brandon Illickal (b) (4)	15 Jan 2021 01:32:28
User entered 'worsening CARDIOVASCULAR DISEASE' reason for change: Data Entry Error	Brandon Illickal (b) (4)	15 Jan 2021 01:28:01
User entered 'cardiovascular disease' reason for change: Data Entry Error	Brandon Illickal (b) (4)	15 Jan 2021 01:27:20
User entered 'DIETARY SUPPLEMENT'	(b) (4), (b) (6)	07 Jan 2021 00:10:37

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User closed query 'Per CDM: Dose per administration should only contain numerals. Please update, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 19:37:14
Query 'Per CDM: Dose per administration should only contain numerals. Please update, thank you.' answered with 'subject takes 1 tab every day' (Site from DM).	Brandon Illickal (b) (4)	15 Jan 2021 01:28:16
User entered '1' reason for change: Data Entry Error	Brandon Illickal (b) (4)	15 Jan 2021 01:26:34
User opened query 'Per CDM: Dose per administration should only contain numerals. Please update, thank you.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 13:57:36
User entered 'DIETARY SUPPLEMANT'	(b) (4), (b) (6)	07 Jan 2021 00:10:37

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:10:37

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'TAB'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:10:37

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:10:37

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:10:37

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:10:37

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:10:37

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'UN May 1997'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:10:37

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:10:37

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:10:37

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:10:37

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:10:37

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Jan 2021 00:10:37

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Jan 2021 00:10:37

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Jan 2021 00:10:37

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
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.	(b) (4) Coder Import (b) (4)	07 Jan 2021 00:12:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Jan 2021 00:12:32
Data point term sent to Coder User entered 'ASPIRIN'	System (b) (4), (b) (6)	07 Jan 2021 00:12:09 07 Jan 2021 00:11:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:11:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'CARDIOVASCULAR DISEASE'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:11:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '81'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:11:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:11:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:11:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:11:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:11:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:11:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:11:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'un May 1997'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:11:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:11:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:11:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:11:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:11:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Jan 2021 00:11:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Jan 2021 00:11:25

US3392049

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Jan 2021 00:11:25

US3392049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:22:36

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:25:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User closed query 'Per ETRTR: According to SAE "Acute Myocardial Infarction" CRF, Concomitant Procedure was performed for SAE. Please add Procedure within this folder or reconcile data from SAE CRF, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:37:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	04 Feb 2021 23:37:17
User entered 'No (N)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	04 Feb 2021 23:36:44
Query 'Per ETRTR: According to SAE "Acute Myocardial Infarction" CRF, Concomitant Procedure was performed for SAE. Please add Procedure within this folder or reconcile data from SAE CRF, thanks.' answered with 'updated' (Site from CRA).	Brandon Illickal (b) (4)	20 Jan 2021 20:11:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	20 Jan 2021 20:11:39
User opened query 'Per ETRTR: According to SAE "Acute Myocardial Infarction" CRF, Concomitant Procedure was performed for SAE. Please add Procedure within this folder or reconcile data from SAE CRF, thanks.' (Site from CRA).	(b) (4), (b) (6)	18 Jan 2021 16:25:28
User entered 'No (N)'	Brandon Illickal (b) (4)	28 Aug 2020 13:22:49

US3392049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:22:36

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '22 Dec 2020'	(b) (4) Brandon Illickal (b) (4)	29 Mar 2021 16:47:50
	[REDACTED]	
	[REDACTED]	

US3392049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:22:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'CARDIAC CATHETERIZATION FOR NON-ST ELEVATED MYOCARDIAL INFARCTION' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:26:02
User entered 'cardiac catheterization'	Brandon Illickal (b) (4)	29 Mar 2021 16:47:50

US3392049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Adverse Event (AE)'	(b) (4) Brandon Illickal (b) (4)	29 Mar 2021 16:47:50
	(b) (4)	
	(b) (4)	

US3392049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	29 Mar 2021 16:47:50

US3392049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:53:48
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:21

US3392049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:22:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:53:48
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'ECHOCARDIOGRAM FOR NON-ST ELEVATED MYOCARDIAL INFARCTION'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:21

US3392049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:53:48
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:21

US3392049

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:53:48
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:21

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'USA-US119-2020-MRNA-1273-P301000013'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'Yes (Y)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'No (N)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'No (N)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'Yes (Y)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'No (N)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'No (N)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'No (N)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'Michael'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'Cotugno'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 19:26:48
User entered 'US'	System	29 Dec 2020 15:18:15

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Jan 2021 19:28:26
User entered '1'	System	29 Dec 2020 15:18:15

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'USA-US119-2020-MRNA-1273-P301000013'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'Yes (Y)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'No (N)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'No (N)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'Yes (Y)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'No (N)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'No (N)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'No (N)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'Michael'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'Cotugno'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 19:26:48
User entered 'US'	System	29 Dec 2020 15:18:15

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Jan 2021 19:28:26
User entered '1'	System	29 Dec 2020 15:18:15

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:22:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
User entered '29/Dec/2020 10:18'	System	29 Dec 2020 15:18:15

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:22:36

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.

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 19:26:48
User entered '1'	(b) (4), (b) (6)	29 Dec 2020 15:18:15

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'USA-US119-2020-MRNA-1273-P301000013'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'Yes (Y)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'No (N)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'No (N)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'Yes (Y)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'No (N)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'No (N)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'No (N)'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'Michael'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'Cotugno'	System	29 Dec 2020 15:17:48

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 19:26:48
User entered 'US'	System	29 Dec 2020 15:18:15

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Jan 2021 19:28:26
User entered '1'	System	29 Dec 2020 15:18:15

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:22:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
User entered '07/Jan/2021 19:28'	System	07 Jan 2021 19:28:26

US3392049

Folder: SAE USA-US119-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:22:36

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.

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:02:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:59:12
User entered '1'	(b) (4), (b) (6)	07 Jan 2021 19:28:26