

US3402211 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3402211

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Participant ID

US3402211

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

US3402211

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	66
Age Units	YEARS
Age (Derived)	67
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:12:01

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 17:12:01

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1958
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1958
Start Year (derived)	1958
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Condition	ENVIRONMENTAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1958
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1958
Start Year (derived)	1958
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Condition	GLAUCOMA BILATERAL
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Condition	LEFT CATARACT
Start date (dd MMM yyyy)	UN FEB 2015
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 FEB 2015
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2015
Start Year (derived)	2015
Stop Month and Year (derived)	FEB 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Condition	RIGHT HIP FRACTURE
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	4 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:25 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 09:25
Height (<i>xxx.x</i>)	168 cm
Weight (<i>xxx.x</i>)	64.1 kg
BMI (<i>xxx.x</i>)	22.71117 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 17:12:01

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Date of assessment (*dd MMM yyyy*) 4 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2011

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:12:01

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

FREQUENT TRAVEL FOR WORK

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) 15 Feb 2021 17:12:01

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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)	False
Other	True
Specify	WHEN TRAVELLING FOR WORK, RESIDES IN APARTMENT COMPLEX

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 184530

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 AUG 2020
Time of assessment (00:00-23:59)	09:25 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 09:25
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 AUG 2020
Time of assessment (00:00-23:59)	10:52 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 10:52
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 4 AUG 2020

What was the treatment time? (00:00-23:59) 10:15 (24 HR)

Treatment Date and Time (derived) 4 AUG 2020 10:15

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 AUG 2020
Collection time (00:00-23:59)	09:51 (24 HR)
Collection date and time (derived)	4 AUG 2020 09:51

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Collection date (dd MMM yyyy)			4 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:35	4 AUG 2020 09:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

04 AUG 2020 10:47

PC Open Date & Time

04 AUG 2020 10:35

PC Close Date & Time

04 AUG 2020 13:05

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 20:34

PC Open Date & Time

04 AUG 2020 14:00

PC Close Date & Time

05 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

05 AUG 2020 21:48

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 21:48

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 22:09

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 22:35

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 21:48

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 23:18

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 10:48

PC Open Date & Time

04 AUG 2020 10:35

PC Close Date & Time

04 AUG 2020 13:05

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 20:35

PC Open Date & Time

04 AUG 2020 14:00

PC Close Date & Time

05 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 21:48

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 21:48

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 22:09

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 22:35

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 21:48

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 23:18

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 10:49
PC Open Date & Time	04 AUG 2020 10:35
PC Close Date & Time	04 AUG 2020 13:05

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 20:36
PC Open Date & Time	04 AUG 2020 14:00
PC Close Date & Time	05 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 21:49
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 21:48
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 22:09
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 22:35
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 21:49
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 23:19
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3402211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402211

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3402211

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:12:00

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402211

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 SEP 2020
Time of assessment (00:00-23:59)	08:31 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 08:31
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)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

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)	1 SEP 2020
Time of assessment (00:00-23:59)	09:32 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 09:32
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	48 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3402211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 SEP 2020

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

US3402211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 1 SEP 2020

What was the treatment time? (00:00-23:59) 08:58 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 08:58

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

US3402211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 SEP 2020
Collection time (00:00-23:59)	08:46 (24 HR)
Collection date and time (derived)	1 SEP 2020 08:46

US3402211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Collection date (dd MMM yyyy)			1 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:45	1 SEP 2020 08:45
Nasopharyngeal Swab 2	No		

US3402211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.3 °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

01 SEP 2020 09:35

PC Open Date & Time

01 SEP 2020 09:18

PC Close Date & Time

01 SEP 2020 11:48

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 21:39

PC Open Date & Time

01 SEP 2020 12:43

PC Close Date & Time

02 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 22:03

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 21:08

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 22:54

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 23:25

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 22:26

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 09:35

PC Open Date & Time

01 SEP 2020 09:18

PC Close Date & Time

01 SEP 2020 11:48

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 21:39

PC Open Date & Time

01 SEP 2020 12:43

PC Close Date & Time

02 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 22:03

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 21:09

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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.**

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 22:54

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 23:26

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 22:26

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 09:36
PC Open Date & Time	01 SEP 2020 09:18
PC Close Date & Time	01 SEP 2020 11:48

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 21:39
PC Open Date & Time	01 SEP 2020 12:43
PC Close Date & Time	02 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 22:03
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 21:10
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

Yes ☐

PC Time stamp

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 22:55
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 23:26
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 22:26
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3402211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402211

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402211

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402211

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3402211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	6 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:54 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 08:54
Temperature (<i>xxx.x</i>)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	55 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3402211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

6 OCT 2020

Collection time (00:00-23:59)

08:57 (24 HR)

Collection date and time (derived)

6 OCT 2020 08:57

US3402211

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:12:01

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	06 OCT 2020 21:59:07
Patient Cloud Open Date & Time	04 OCT 2020 00:01
Patient Cloud Close Date & Time	08 OCT 2020 23:59

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 OCT 2020 21:55:46

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 OCT 2020 22:18:33

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 NOV 2020 23:18:15
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 99
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	09 NOV 2020 08:14:16
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 11:38:48

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 08:05:14
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 19:57:57
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 DEC 2020 12:00:27

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 16:00:33

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 15:33:55

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 21:32:32

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 12:24:59

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 22:01:52
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 21:24:43

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 22:52:30

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	30 JAN 2021 10:49:28
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 12:22:41

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 FEB 2021 11:14:43
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 FEB 2021 12:00:19
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 17:08:17

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 18:24:22

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	12 MAR 2021 10:07:59
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	19 MAR 2021 10:31:39
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 10:29:11

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 14:01:37

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	17 APR 2021 12:01:56
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 14:04:02

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 299

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 313

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 362

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

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

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

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

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

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

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 ☐

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 369

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

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

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

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

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

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

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 ☐

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 474

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 481

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 502

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 537
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 551

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

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

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

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

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

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 572

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 579

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 586

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

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

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

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

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

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

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 ☐

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 628

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 677

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 726

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 754

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 775

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

DAY 782

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

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

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

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

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

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

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 ☐

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3402211

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:30:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 17:08:25

US3402211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:20:35

Generated On: 09 Jun 2021 17:30:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402211

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:20:35

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402211

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402211

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3402211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 MAR 2021
Time of assessment (00:00-23:59)	08:50 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 08:50
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3402211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 MAR 2021

Collection time (00:00-23:59)

08:56 (24 HR)

Collection date and time (derived)

3 MAR 2021 08:56

US3402211

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402211

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402211

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402211

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402211

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:30:30

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3402211

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:30:30

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3402211

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

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

Visit date (dd MMM yyyy)	08 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3402211

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Date of updated informed consent (<i>dd MMM yyyy</i>)	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	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

US3402211

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

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

US3402211

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 JAN 2021
Time of assessment (00:00-23:59)	09:23 (24 HR)
Vital Signs Date and Time (derived)	08 JAN 2021 09:23
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3402211

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 JAN 2021
Time of assessment (00:00-23:59)	10:46 (24 HR)
Vital Signs Date and Time (derived)	08 JAN 2021 10:46
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3402211

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

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

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.

US3402211

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

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 08 JAN 2021

What was the treatment time? (00:00-23:59) 09:45 (24 HR)

Treatment Date and Time (derived) 08 JAN 2021 09:45

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

What was the frequency of the study treatment dosing? ONCE

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

US3402211

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 JAN 2021

Collection time (00:00-23:59)

09:16 (24 HR)

Collection date and time (derived)

08 JAN 2021 09:16

US3402211

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 JAN 2021
Collection time (00:00 - 23:59)	09:09
Collection Date and Time (derived)	08 JAN 2021 09:09

US3402211

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

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 FEB 2021
Time of assessment (00:00-23:59)	12:17 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 12:17
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

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)	5 FEB 2021
Time of assessment (00:00-23:59)	13:25 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 13:25
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3402211

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 FEB 2021

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

US3402211

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 5 FEB 2021

What was the treatment time? (00:00-23:59) 12:50 (24 HR)

Treatment Date and Time (derived) 5 FEB 2021 12:50

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

What was the frequency of the study treatment dosing? ONCE

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

US3402211

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402211

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402211

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

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Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	3 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	08:50 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 08:50
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	54 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 MAR 2021

Collection time (00:00-23:59)

08:56 (24 HR)

Collection date and time (derived)

3 MAR 2021 08:56

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 14:39:44

Generated On: 09 Jun 2021 17:30:30

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

AEID

Adverse event

URINARY TRACT INFECTION

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)

07 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

AEID	
Adverse event	INTERMITTEN ELEVATED A1C
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

AEID	USA-US059-2020-MRNA-1273-P30 1000026
Adverse event	DUCTAL CARCINOMA INSITU RIGHT BREAST
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 23:31:26

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

Narrative

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

LUMP WAS DISCOVERED ON
MAMMOGRAM PERFORMED
23OCT2020. DUCTAL
CARCINOMA INSITU RIGHT
BREAST WAS DIAGNOSED
19NOV2020. SUBJECT HAD
LUMPECTOMY 23DEC2020.
SUBJECTS PATHLOGY SHOWED
LOBULAR CARCINOMA IN SITU

Serious Adverse Event Derived (CSA Programming Field Only)	1
--	---

Medically Attended AE Derived (CSA Programming Field Only)	1
--	---

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

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

Name of Medication ALLERGY SHOTS: RAGWEED
AND MOLD

Prophylaxis Yes ☐
No ☒

Indication ENVIRONMENTAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify SHOT

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input checked="" type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

Name of Medication BIMATOPROST

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA BILATERAL

Dose per administration 1

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

If dose unit is Other, specify DROP

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	DROP	
Start date (dd MMM yyyy)	UN UNK 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

Name of Medication BRINZOLAMIDE/BRIMONIDINE
TARTRATE

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA BILATERAL

Dose per administration 2

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

If dose unit is Other, specify DROPS

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

	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 UNK 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

Name of Medication KEFLEX

Prophylaxis Yes ☐
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

	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)		7 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3402211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 23:31:26

Generated On: 09 Jun 2021 17:30:30

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
19 NOV 2020	RIGHT BREAST BIOPSY	Adverse Event	
23 DEC 2020	RIGHT BREAST LUMPECTOMY	Adverse Event	
23 OCT 2020	MAMMOGRAM	Diagnostic	

US3402211

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:30:30

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

US3402211

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:30:30

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

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

SAEID	USA-US059-2020-MRNA-1273-P301000026
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

SAEID	USA-US059-2020-MRNA-1273-P301000026
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	30/DEC/2020 15:15
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

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

SAEID	USA-US059-2020-MRNA-1273-P301000026
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	07/JAN/2021 18:47
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

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

SAEID	USA-US059-2020-MRNA-1273-P301000026
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	20/JAN/2021 12:33
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

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 22:49:19

Generated On: 09 Jun 2021 17:30:30

SAEID	USA-US059-2020-MRNA-1273-P301000026
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/MAR/2021 07:25
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

US3402211 (Prod: Meridian Clinical Research, LLC)

US3402211

Form: Participant Creation

Generated On: 09 Jun 2021 17:30:30

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'US3402211'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:14:24

US3402211

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:18:05

US3402211

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:14:25

US3402211

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Clinic (Clinic)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:18:05

US3402211

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'SCRN'	System	04 Aug 2020 17:18:05

US3402211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered (b) (6) 1953'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:14:26

US3402211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:30

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '66'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:18:19

US3402211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:30

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'YEARS'	System	04 Aug 2020 17:18:19

US3402211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:30

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered '67'	System	04 Aug 2020 14:29:18

US3402211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:30

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Female (F)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:18:19

US3402211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:30

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:18:19

US3402211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:30

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'I'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:18:19

US3402211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:30

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:18:19

US3402211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:30

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:18:19

US3402211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:30

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:18:19

US3402211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:30

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:18:19

US3402211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:18:19

US3402211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:30

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:18:19

US3402211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:30

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:18:19

US3402211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:30:30

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:18:19

US3402211

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 14:29:18

US3402211

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'Aug 2020'	System	04 Aug 2020 14:29:18

US3402211

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered '2020'	System	04 Aug 2020 14:29:18

US3402211

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:30

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Amendment 1 (1)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 14:29:18

US3402211

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 14:29:18
	(b) (4)	

US3402211

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 14:29:18

US3402211

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:30

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 14:29:18

US3402211

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:30

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 14:29:18
	(b) (4)	

US3402211

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:30

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:14:25

US3402211

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:30:30

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'I'	System	04 Aug 2020 14:29:22

US3402211

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 14:29:22

US3402211

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:30:30

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:18:49

US3402211

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Aug 2020 17:21:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 17:21:03
Data point term sent to Coder	System	04 Aug 2020 17:20:50
User entered 'SEASONAL ALLERGIES'	Tarin Gordon (b) (4)	04 Aug 2020 17:20:03
	(b) (4)	

US3402211

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'UN UNK 1958'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:20:03

US3402211

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:20:03

US3402211

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:20:03

US3402211

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:20:03

US3402211

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:20:03

US3402211

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'Jan 1958'	System	04 Aug 2020 17:20:03

US3402211

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered '1958'	System	04 Aug 2020 17:20:03

US3402211

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered empty.	System	04 Aug 2020 17:20:03

US3402211

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered empty.	System	04 Aug 2020 17:20:03

US3402211

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:30:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 17:21:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 17:21:03
Data point term sent to Coder	System	04 Aug 2020 17:20:49
User entered 'ENVIRONMENTAL ALLERGIES'	Tarin Gordon (b) (4)	04 Aug 2020 17:20:28

US3402211

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'UN UNK 1958'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:20:28

US3402211

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:30:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:20:28

US3402211

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:30:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:20:28

US3402211

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:20:28

US3402211

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:30:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:20:28

US3402211

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'Jan 1958'	System	04 Aug 2020 17:20:28

US3402211

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered '1958'	System	04 Aug 2020 17:20:28

US3402211

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered empty.	System	04 Aug 2020 17:20:28

US3402211

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered empty.	System	04 Aug 2020 17:20:28

US3402211

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User closed query 'Please update the Condition term to GLAUCOMA BILATERAL per the previous response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:08:16
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma both eyes - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 12:44:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 12:44:51
Query 'Please update the Condition term to GLAUCOMA BILATERAL per the previous response.' answered with 'GLAUCOMA BILATERAL' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	24 Sep 2020 12:44:00
Data point term sent to Coder	System	24 Sep 2020 12:43:59
Coding entries removed.	Tammy Kohn (b) (4) (b) (4)	24 Sep 2020 12:43:54
User entered 'GLAUCOMA BILATERAL' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	24 Sep 2020 12:43:54
User opened query 'Please update the Condition term to GLAUCOMA BILATERAL per the previous response.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:43:35
User closed query 'Per DM CLR: Please update the condition to include the laterality of GLAUCOMA (e.g. Left, Right or Bilateral Glaucoma). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:43:35
Query 'Per DM CLR: Please update the condition to include the laterality of GLAUCOMA (e.g. Left, Right or Bilateral Glaucoma). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'GLAUCOMA BILATERIAL' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	22 Sep 2020 18:32:55

US3402211

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:30

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the condition to include the laterality of GLAUCOMA (e.g. Left, Right or Bilateral Glaucoma). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 20:50:07
User coded data point as SOC: Eye disorders, HLGT: Coder Import Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\\23.0.	(b) (4)	04 Aug 2020 17:23:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 17:23:12
Data point term sent to Coder	System	04 Aug 2020 17:21:50
User entered 'GLAUCOMA'	Tarin Gordon (b) (4)	04 Aug 2020 17:20:50

US3402211

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'UN UNK 2011'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:20:50

US3402211

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:20:50

US3402211

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:20:50

US3402211

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:20:50

US3402211

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:20:50

US3402211

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'Jan 2011'	System	04 Aug 2020 17:20:50

US3402211

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered '2011'	System	04 Aug 2020 17:20:50

US3402211

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered empty.	System	04 Aug 2020 17:20:50

US3402211

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered empty.	System	04 Aug 2020 17:20:50

US3402211

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:30:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Left cataract - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	04 Aug 2020 17:23:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 17:23:13
Data point term sent to Coder	System	04 Aug 2020 17:21:50
User entered 'LEFT CATARACT'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:21:30

US3402211

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'UN Feb 2015'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:21:30

US3402211

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:30:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:21:30

US3402211

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:30:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:21:30

US3402211

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'UN Feb 2015'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:21:30

US3402211

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:30:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:21:30

US3402211

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'Feb 2015'	System	04 Aug 2020 17:21:30

US3402211

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered '2015'	System	04 Aug 2020 17:21:30

US3402211

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'Feb 2015'	System	04 Aug 2020 17:21:30

US3402211

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered '2015'	System	04 Aug 2020 17:21:30

US3402211

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:30:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Right cataract - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	04 Aug 2020 17:23:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 17:23:12
Data point term sent to Coder	System	04 Aug 2020 17:21:50
User entered 'RIGHT CATARACT'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:21:50

US3402211

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'UN UNK 2019'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:21:50

US3402211

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:30:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:21:50

US3402211

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:30:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:21:50

US3402211

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:21:50

US3402211

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:30:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:21:50

US3402211

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'Jan 2019'	System	04 Aug 2020 17:21:50

US3402211

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered '2019'	System	04 Aug 2020 17:21:50

US3402211

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered empty.	System	04 Aug 2020 17:21:50

US3402211

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered empty.	System	04 Aug 2020 17:21:50

US3402211

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:30:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	04 Aug 2020 17:24:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 17:24:02
Data point term sent to Coder	System	04 Aug 2020 17:22:51
User entered 'HYPERLIPIDEMIA'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:22:07

US3402211

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'UN UNK 2003'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:22:07

US3402211

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:30:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:22:07

US3402211

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:30:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:22:07

US3402211

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:22:07

US3402211

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:30:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:22:07

US3402211

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'Jan 2003'	System	04 Aug 2020 17:22:07

US3402211

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered '2003'	System	04 Aug 2020 17:22:07

US3402211

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered empty.	System	04 Aug 2020 17:22:07

US3402211

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered empty.	System	04 Aug 2020 17:22:07

US3402211

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:30:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	04 Aug 2020 17:24:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 17:24:03
Data point term sent to Coder	System	04 Aug 2020 17:22:52
User entered 'OSTEOPOROSIS'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:22:26

US3402211

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'UN UNK 2010'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:22:26

US3402211

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:30:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:22:26

US3402211

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:30:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:22:26

US3402211

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:22:26

US3402211

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:30:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:22:26

US3402211

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'Jan 2010'	System	04 Aug 2020 17:22:26

US3402211

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered '2010'	System	04 Aug 2020 17:22:26

US3402211

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered empty.	System	04 Aug 2020 17:22:26

US3402211

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered empty.	System	04 Aug 2020 17:22:26

US3402211

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:30:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Hip fracture - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:04:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:04:18
Data point term sent to Coder	System	04 Aug 2020 17:22:52
User entered 'RIGHT HIP FRACTURE'	Tarin Gordon (b) (4)	04 Aug 2020 17:22:51

US3402211

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'UN UNK 2012'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:22:51

US3402211

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:30:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:22:51

US3402211

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:30:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:22:51

US3402211

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please correct dates or provide explanation for the Med History duration. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:56:24
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please correct dates or provide explanation for the Med History duration. Otherwise, clarify. ' answered with 'ARTIFICIAL HIP REPLACEMENT' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	22 Sep 2020 18:34:56
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please correct dates or provide explanation for the Med History duration. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 20:51:20
User entered 'UN UNK 2013'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:22:51

US3402211

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:30:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:22:51

US3402211

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'Jan 2012'	System	04 Aug 2020 17:22:51

US3402211

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered '2012'	System	04 Aug 2020 17:22:51

US3402211

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'Jan 2013'	System	04 Aug 2020 17:22:51

US3402211

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered '2013'	System	04 Aug 2020 17:22:51

US3402211

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:30:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 17:25:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 17:25:10
Data point term sent to Coder	System	04 Aug 2020 17:23:53
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Tarin Gordon (b) (4)	04 Aug 2020 17:23:15

US3402211

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'UN UNK 2009'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:23:15

US3402211

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:30:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:23:15

US3402211

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:30:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:23:15

US3402211

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:23:15

US3402211

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:30:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:23:15

US3402211

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'Jan 2009'	System	04 Aug 2020 17:23:15

US3402211

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered '2009'	System	04 Aug 2020 17:23:15

US3402211

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered empty.	System	04 Aug 2020 17:23:15

US3402211

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered empty.	System	04 Aug 2020 17:23:15

US3402211

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:30:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User closed query 'CDM RQ: Per previous response, please update the Conmeds page to record the corresponding medication with Indication of Chronic Bronchitis.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:28:37
Query 'CDM RQ: Per previous response, please update the Conmeds page to record the corresponding medication with Indication of Chronic Bronchitis.' answered with 'Subject is not currently on any medications for this condition' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	02 Oct 2020 20:36:51
User opened query 'CDM RQ: Per previous response, please update the Conmeds page to record the corresponding medication with Indication of Chronic Bronchitis.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:05:25
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:05:25
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'CHRONIC BRONCHITIS TREATED WITH ALLERGY SHOTS.' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	22 Sep 2020 18:37:17
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 20:52:30

US3402211

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:30:30

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Bronchitis chronic, LLT: Chronic bronchitis - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 17:25:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 17:25:09
Data point term sent to Coder	System	04 Aug 2020 17:23:53
User entered 'CHRONIC BRONCHITIS'	Tarin Gordon (b) (4)	04 Aug 2020 17:23:43

US3402211

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'UN UNK 2000'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:23:43

US3402211

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:30:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:23:43

US3402211

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:30:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 17:29:57
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 17:23:43
	(b) (4)	

US3402211

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty; reason for change Data Entry Error	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 17:29:57
User entered 'UN UNK 2018'	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 17:23:43
	(b) (4)	

US3402211

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:30:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:23:43

US3402211

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'Jan 2000'	System	04 Aug 2020 17:23:43

US3402211

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered '2000'	System	04 Aug 2020 17:23:43

US3402211

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered empty.	System	04 Aug 2020 17:29:57
User entered 'Jan 2018'	System	04 Aug 2020 17:23:43

US3402211

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered empty.	System	04 Aug 2020 17:29:57
User entered '2018'	System	04 Aug 2020 17:23:43

US3402211

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:30:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	04 Aug 2020 17:32:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 17:32:09
Data point term sent to Coder	System	04 Aug 2020 17:31:00
User entered 'POST-MENOPAUSAL'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:30:25

US3402211

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'UN UNK 2011'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:30:25

US3402211

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:30:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:30:25

US3402211

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:30:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:30:25

US3402211

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:30:25

US3402211

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:30:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:30:25

US3402211

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'Jan 2011'	System	04 Aug 2020 17:30:25

US3402211

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered '2011'	System	04 Aug 2020 17:30:25

US3402211

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered empty.	System	04 Aug 2020 17:30:25

US3402211

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered empty.	System	04 Aug 2020 17:30:25

US3402211

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:30:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52

US3402211

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52

US3402211

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:30:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52

US3402211

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:30:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52

US3402211

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52

US3402211

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:30:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52

US3402211

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52

US3402211

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52

US3402211

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52

US3402211

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:24:50

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:24:50

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '09:25'	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 17:24:50
	(b) (4)	

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered '4 Aug 2020 09:25'	System	04 Aug 2020 17:24:50

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '168' cm	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 17:24:50
DataPoint set to visible.	(b) (4)	
	System	04 Aug 2020 14:29:22

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '64.1' kg	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 17:24:50
DataPoint set to visible.	(b) (4)	
	System	04 Aug 2020 14:29:22

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
Amendment Manager: User entered '22.71117'	System	16 Sep 2020 23:42:07
User entered '22.7'	System	04 Aug 2020 17:24:50
DataPoint set to visible.	System	04 Aug 2020 14:29:22

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'kg/m2'	System	04 Aug 2020 17:24:50
DataPoint set to visible.	System	04 Aug 2020 14:29:22

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:34:44
User entered '36.9' C	Tarin Gordon (b) (4)	04 Aug 2020 17:24:50
	(b) (4)	

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty; reason for change Data Entry Error	(b) (4)	
	Tammy Kohn (b) (4)	20 Dec 2020 16:34:44
	(b) (4)	
User entered 'Oral (Oral)'	Tarin Gordon (b) (4)	04 Aug 2020 17:24:50
	(b) (4)	

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:24:50

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:34:44
User entered '60'	Tarin Gordon (b) (4)	04 Aug 2020 17:24:50
	(b) (4)	

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'bpm'	System	04 Aug 2020 17:24:50

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:34:44
User entered '16'	Tarin Gordon (b) (4)	04 Aug 2020 17:24:50
	(b) (4)	

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'breaths/min'	System	04 Aug 2020 17:24:50

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:34:44
User entered '126'	Tarin Gordon (b) (4)	04 Aug 2020 17:24:50
	(b) (4)	

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'mmHg'	System	04 Aug 2020 17:24:50

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:34:44
User entered '84'	Tarin Gordon (b) (4)	04 Aug 2020 17:24:50
	(b) (4)	

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User entered 'mmHg'	System	04 Aug 2020 17:24:50

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52

US3402211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52

US3402211

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4)	04 Aug 2020 17:25:05
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402211

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	06 Sep 2020 12:39:00
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 13:30:09
User entered '4 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:25:05

US3402211

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:30:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:26:06

US3402211

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:26:06

US3402211

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:30:30

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:26:06

US3402211

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:26:06

US3402211

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:26:06

US3402211

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:30:30

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:26:06

US3402211

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'UN UNK 2011'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:26:06

US3402211

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:30:30

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:26:06

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'FREQUENT TRAVEL FOR WORK'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '0'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'I'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:30:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:30:52
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'WHEN TRAVELLING FOR WORK, RESIDES IN APARTMENT COMPLEX'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:27:53

US3402211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4)	04 Aug 2020 17:28:08
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:28:08

US3402211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Clinic (Clinic)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:28:08

US3402211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'VISIT1'	System	04 Aug 2020 17:28:08

US3402211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:14:26

US3402211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:30

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 01:53:45
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:53:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 13:14:26
User entered '184530' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:14:26

US3402211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:14:26

US3402211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	04 Aug 2020 17:29:25

US3402211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	Tarin Gordon (b) (4)	04 Aug 2020 17:29:25

US3402211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:29:25

US3402211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:29:25

US3402211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:30:30

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:29:25

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:34:22
User entered '168' cm	Tarin Gordon (b) (4)	04 Aug 2020 17:31:56
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:34:22
User entered '64.1' kg	Tarin Gordon (b) (4)	04 Aug 2020 17:31:56
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:34:22
User entered '168' cm	Tarin Gordon (b) (4)	04 Aug 2020 17:31:56
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:34:22
User entered '64.1' kg	Tarin Gordon (b) (4)	04 Aug 2020 17:31:56
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User accepted default value 'Pre-Dose (PREDOSE)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 17:31:56
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '09:25'	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 17:31:56
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered '4 Aug 2020 09:25'	System	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '36.9' C	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Oral (Oral)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 17:31:56
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '60'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'bpm'	System	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '16'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:31:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'breaths/min'	System	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '126'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'mmHg'	System	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '84'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'mmHg'	System	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:34:22
User entered '168' cm	Tarin Gordon (b) (4)	04 Aug 2020 17:31:56
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:34:22
User entered '64.1' kg	Tarin Gordon (b) (4)	04 Aug 2020 17:31:56
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User accepted default value 'Post-Dose (POSTDOSE)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 15:24:23
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 MIN' (Site from System).	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:32:04
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		04 Aug 2020 17:31:56
User entered '10:52'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:31:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered '4 Aug 2020 10:52'	System	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '37.0' C	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 17:31:56
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Oral (Oral)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:31:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:31:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '60'	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 17:31:56
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'bpm'	System	04 Aug 2020 17:31:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '16'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'breaths/min'	System	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '120'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'mmHg'	System	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '82'	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 17:31:56
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'mmHg'	System	04 Aug 2020 17:31:56

US3402211

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 17:32:13
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:30

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:32:13

US3402211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 14:29:46

US3402211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 14:29:46
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	Tarin Gordon (b) (4)	04 Aug 2020 14:29:46

US3402211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 14:29:46

US3402211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '4 Aug 2020'	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 14:29:46
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '10:15'	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 14:29:46
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered '4 Aug 2020 10:15'	System	04 Aug 2020 14:29:46

US3402211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Left Arm (LEFT ARM)'	Tarin Gordon (b) (4)	04 Aug 2020 14:29:46

US3402211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'ONCE'	System	04 Aug 2020 14:29:46

US3402211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 14:29:46

US3402211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 17:32:45
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:32:45

US3402211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '09:51'	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 17:32:45
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered '4 Aug 2020 09:51'	System	04 Aug 2020 17:32:45

US3402211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:30:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:33:03

US3402211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:30:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:33:03

US3402211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:30:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:33:03

US3402211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:30:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '09:35'	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 17:33:03
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered '4 Aug 2020 09:35'	System	04 Aug 2020 17:33:03

US3402211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:33:03

US3402211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:33:03

US3402211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 17:33:03

US3402211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered empty.	System	04 Aug 2020 17:33:03

US3402211

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 17:33:07
	(b) (4)	

US3402211

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered '1'	System	04 Aug 2020 17:33:07

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T10:46:44', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '8b0d0cb7-0266-4ee1-98cd-b5dd025b8938' User entered 'Yes (Y)'	System	04 Aug 2020 14:47:11
	System	04 Aug 2020 14:47:11

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T10:46:56', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '8b0d0cb7-0266-4ee1-98cd-b5dd025b8938' User entered '98.6'	System	04 Aug 2020 14:47:11
	System	04 Aug 2020 14:47:11

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T10:47:02', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '8b0d0cb7-0266-4ee1-98cd-b5dd025b8938'	System	04 Aug 2020 14:47:11
User entered 'No (N)'	System	04 Aug 2020 14:47:11

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T10:47:08', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '8b0d0cb7-0266-4ee1-98cd-b5dd025b8938' User entered '04 Aug 2020 10:47'	System	04 Aug 2020 14:47:11
	System	04 Aug 2020 14:47:11

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '04 Aug 2020 10:35'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '04 Aug 2020 13:05'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T20:34:16', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e9c55b88-c15e-4b46-ad9c-1aed731f1507'	System	05 Aug 2020 00:34:36
User entered 'Yes (Y)'	System	05 Aug 2020 00:34:36

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T20:34:24', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e9c55b88-c15e-4b46-ad9c-1aed731f1507' User entered '98.2'	System	05 Aug 2020 00:34:36
	System	05 Aug 2020 00:34:36

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T20:34:28', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e9c55b88-c15e-4b46-ad9c-1aed731f1507'	System	05 Aug 2020 00:34:36
User entered 'No (N)'	System	05 Aug 2020 00:34:36

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T20:34:35', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e9c55b88-c15e-4b46-ad9c-1aed731f1507'	System	05 Aug 2020 00:34:36
User entered '04 Aug 2020 20:34'	System	05 Aug 2020 00:34:36

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '04 Aug 2020 14:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 2'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-05T21:48:02', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '1e10af24-2f37-4e42-802b-1431507ab427' User entered 'Yes (Y)'	System	06 Aug 2020 01:48:30
	System	06 Aug 2020 01:48:30

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-05T21:48:20', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '1e10af24-2f37-4e42-802b-1431507ab427' User entered '98.3'	System	06 Aug 2020 01:48:30
	System	06 Aug 2020 01:48:30

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-05T21:48:23', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '1e10af24-2f37-4e42-802b-1431507ab427'	System	06 Aug 2020 01:48:30
User entered 'No (N)'	System	06 Aug 2020 01:48:30

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-05T21:48:28', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '1e10af24-2f37-4e42-802b-1431507ab427'	System	06 Aug 2020 01:48:30
User entered '05 Aug 2020 21:48'	System	06 Aug 2020 01:48:30

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 3'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-06T21:47:49', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f38c266b-6048-4231-8525-25d50319cd8e' User entered 'Yes (Y)'	System	07 Aug 2020 01:48:06
	System	07 Aug 2020 01:48:06

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-06T21:47:54', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f38c266b-6048-4231-8525-25d50319cd8e' User entered '98.0'	System	07 Aug 2020 01:48:06
	System	07 Aug 2020 01:48:06

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-06T21:47:56', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f38c266b-6048-4231-8525-25d50319cd8e' User entered 'No (N)'	System	07 Aug 2020 01:48:06
	System	07 Aug 2020 01:48:06

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-06T21:48:03', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f38c266b-6048-4231-8525-25d50319cd8e' User entered '06 Aug 2020 21:48'	System	07 Aug 2020 01:48:06
	System	07 Aug 2020 01:48:06

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 4'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-07T22:08:58', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e90c9647-d81a-467a-acf2-9d0145b5ea1e' User entered 'Yes (Y)'	System	08 Aug 2020 02:09:12
	System	08 Aug 2020 02:09:12

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-07T22:09:02', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e90c9647-d81a-467a-acf2-9d0145b5ea1e' User entered '97.5'	System	08 Aug 2020 02:09:12
	System	08 Aug 2020 02:09:12

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-07T22:09:04', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e90c9647-d81a-467a-acf2-9d0145b5ea1e' User entered 'No (N)'	System	08 Aug 2020 02:09:12
	System	08 Aug 2020 02:09:12

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-07T22:09:09', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e90c9647-d81a-467a-acf2-9d0145b5ea1e' User entered '07 Aug 2020 22:09'	System	08 Aug 2020 02:09:12
	System	08 Aug 2020 02:09:12

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 5'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-08T22:35:08', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '2b978674-4483-4eb4-9579-21d6acfc4abd' User entered 'Yes (Y)'	System	09 Aug 2020 02:35:21
	System	09 Aug 2020 02:35:21

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-08T22:35:12', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '2b978674-4483-4eb4-9579-21d6acfc4abd' User entered '97.7'	System	09 Aug 2020 02:35:21
	System	09 Aug 2020 02:35:21

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-08T22:35:15', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '2b978674-4483-4eb4-9579-21d6acfc4abd' User entered 'No (N)'	System	09 Aug 2020 02:35:21
	System	09 Aug 2020 02:35:21

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-08T22:35:19', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '2b978674-4483-4eb4-9579-21d6acfc4abd' User entered '08 Aug 2020 22:35'	System	09 Aug 2020 02:35:21
	System	09 Aug 2020 02:35:21

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 6'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-09T21:48:12', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'c0f78c5b-7ed3-42d6-b05f-66cec5dd404e' User entered 'Yes (Y)'	System	10 Aug 2020 01:48:24
	System	10 Aug 2020 01:48:24

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-09T21:48:16', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'c0f78c5b-7ed3-42d6-b05f-66cec5dd404e' User entered '98.0'	System	10 Aug 2020 01:48:24
	System	10 Aug 2020 01:48:24

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-09T21:48:18', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'c0f78c5b-7ed3-42d6-b05f-66cec5dd404e' User entered 'No (N)'	System	10 Aug 2020 01:48:24
	System	10 Aug 2020 01:48:24

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-09T21:48:22', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'c0f78c5b-7ed3-42d6-b05f-66cec5dd404e' User entered '09 Aug 2020 21:48'	System	10 Aug 2020 01:48:24
	System	10 Aug 2020 01:48:24

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 7'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-10T23:18:03', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '0cce4627-c048-4af2-9060-d42b145004cc' User entered 'Yes (Y)'	System	11 Aug 2020 03:18:22
	System	11 Aug 2020 03:18:22

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-10T23:18:09', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '0cce4627-c048-4af2-9060-d42b145004cc' User entered '97.5'	System	11 Aug 2020 03:18:22
	System	11 Aug 2020 03:18:22

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-10T23:18:12', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '0cce4627-c048-4af2-9060-d42b145004cc' User entered 'No (N)'	System	11 Aug 2020 03:18:22
	System	11 Aug 2020 03:18:22

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-10T23:18:17', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '0cce4627-c048-4af2-9060-d42b145004cc' User entered '10 Aug 2020 23:18'	System	11 Aug 2020 03:18:22
	System	11 Aug 2020 03:18:22

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T10:47:39', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'cbf20443-84f7-413b-ba91-301566e80833'	System	04 Aug 2020 14:48:05
User entered 'None (1)'	System	04 Aug 2020 14:48:05

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T10:47:42', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'cbf20443-84f7-413b-ba91-301566e80833' User entered 'No (N)'	System	04 Aug 2020 14:48:05
	System	04 Aug 2020 14:48:05

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T10:47:49', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'cbf20443-84f7-413b-ba91-301566e80833'	System	04 Aug 2020 14:48:05
User entered 'No (N)'	System	04 Aug 2020 14:48:05

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T10:47:57', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'cbf20443-84f7-413b-ba91-301566e80833'	System	04 Aug 2020 14:48:05
User entered 'None (1)'	System	04 Aug 2020 14:48:05

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T10:48:04', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'cbf20443-84f7-413b-ba91-301566e80833' User entered '04 Aug 2020 10:48'	System	04 Aug 2020 14:48:05
	System	04 Aug 2020 14:48:05

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '04 Aug 2020 10:35'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '04 Aug 2020 13:05'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T20:34:40', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '17719f54-cb9c-4ad9-964a-ad222e6a95c1' User entered 'None (1)'	System	05 Aug 2020 00:35:23
	System	05 Aug 2020 00:35:23

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T20:34:43', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '17719f54-cb9c-4ad9-964a-ad222e6a95c1' User entered 'No (N)'	System	05 Aug 2020 00:35:23
	System	05 Aug 2020 00:35:23

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T20:34:54', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '17719f54-cb9c-4ad9-964a-ad222e6a95c1' User entered 'No (N)'	System	05 Aug 2020 00:35:23
	System	05 Aug 2020 00:35:23

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T20:35:12', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '17719f54-cb9c-4ad9-964a-ad222e6a95c1' User entered 'None (1)'	System	05 Aug 2020 00:35:23
	System	05 Aug 2020 00:35:23

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T20:35:19', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '17719f54-cb9c-4ad9-964a-ad222e6a95c1' User entered '04 Aug 2020 20:35'	System	05 Aug 2020 00:35:23
	System	05 Aug 2020 00:35:23

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '04 Aug 2020 14:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 2'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-05T21:48:32', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e0200936-5ba2-47fd-b8ad-bcd0a889dc61' User entered 'None (1)'	System	06 Aug 2020 01:48:49
	System	06 Aug 2020 01:48:49

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-05T21:48:35', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e0200936-5ba2-47fd-b8ad-bcd0a889dc61' User entered 'No (N)'	System	06 Aug 2020 01:48:49
	System	06 Aug 2020 01:48:49

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-05T21:48:37', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e0200936-5ba2-47fd-b8ad-bcd0a889dc61' User entered 'No (N)'	System	06 Aug 2020 01:48:49
	System	06 Aug 2020 01:48:49

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-05T21:48:40', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e0200936-5ba2-47fd-b8ad-bcd0a889dc61' User entered 'None (1)'	System	06 Aug 2020 01:48:49
	System	06 Aug 2020 01:48:49

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-05T21:48:45', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e0200936-5ba2-47fd-b8ad-bcd0a889dc61' User entered '05 Aug 2020 21:48'	System	06 Aug 2020 01:48:49
	System	06 Aug 2020 01:48:49

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 3'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-06T21:48:13', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ccb91be9-0f18-48ee-968c-afa7a452a8e9' User entered 'None (1)'	System	07 Aug 2020 01:48:30
	System	07 Aug 2020 01:48:30

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-06T21:48:16', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ccb91be9-0f18-48ee-968c-afa7a452a8e9' User entered 'No (N)'	System	07 Aug 2020 01:48:30
	System	07 Aug 2020 01:48:30

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-06T21:48:17', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ccb91be9-0f18-48ee-968c-afa7a452a8e9' User entered 'No (N)'	System	07 Aug 2020 01:48:30
	System	07 Aug 2020 01:48:30

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-06T21:48:24', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ccb91be9-0f18-48ee-968c-afa7a452a8e9' User entered 'None (1)'	System	07 Aug 2020 01:48:30
	System	07 Aug 2020 01:48:30

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-06T21:48:28', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ccb91be9-0f18-48ee-968c-afa7a452a8e9' User entered '06 Aug 2020 21:48'	System	07 Aug 2020 01:48:30
	System	07 Aug 2020 01:48:30

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 4'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-07T22:09:13', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'b666ddaa-f19f-4a47-906b-f63c85e179cc' User entered 'None (1)'	System	08 Aug 2020 02:09:38
	System	08 Aug 2020 02:09:38

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-07T22:09:18', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'b666ddaa-f19f-4a47-906b-f63c85e179cc' User entered 'No (N)'	System	08 Aug 2020 02:09:38
	System	08 Aug 2020 02:09:38

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-07T22:09:20', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'b666ddaa-f19f-4a47-906b-f63c85e179cc' User entered 'No (N)'	System	08 Aug 2020 02:09:38

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-07T22:09:29', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'b666ddaa-f19f-4a47-906b-f63c85e179cc' User entered 'None (1)'	System	08 Aug 2020 02:09:38
	System	08 Aug 2020 02:09:38

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-07T22:09:33', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'b666ddaa-f19f-4a47-906b-f63c85e179cc' User entered '07 Aug 2020 22:09'	System	08 Aug 2020 02:09:38
	System	08 Aug 2020 02:09:38

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 5'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-08T22:35:24', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '4080fc30-63bd-4b6d-b9a1-f10f7ba69e34' User entered 'None (1)'	System	09 Aug 2020 02:35:37
	System	09 Aug 2020 02:35:37

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-08T22:35:26', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '4080fc30-63bd-4b6d-b9a1-f10f7ba69e34' User entered 'No (N)'	System	09 Aug 2020 02:35:37
	System	09 Aug 2020 02:35:37

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-08T22:35:28', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '4080fc30-63bd-4b6d-b9a1-f10f7ba69e34' User entered 'No (N)'	System	09 Aug 2020 02:35:37

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-08T22:35:30', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '4080fc30-63bd-4b6d-b9a1-f10f7ba69e34' User entered 'None (1)'	System	09 Aug 2020 02:35:37
	System	09 Aug 2020 02:35:37

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-08T22:35:34', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '4080fc30-63bd-4b6d-b9a1-f10f7ba69e34' User entered '08 Aug 2020 22:35'	System	09 Aug 2020 02:35:37
	System	09 Aug 2020 02:35:37

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 6'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-09T21:48:26', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '59a72512-c575-452f-99a9-825f5d5ea908' User entered 'None (1)'	System	10 Aug 2020 01:48:40
	System	10 Aug 2020 01:48:40

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-09T21:48:29', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '59a72512-c575-452f-99a9-825f5d5ea908'	System	10 Aug 2020 01:48:40
User entered 'No (N)'	System	10 Aug 2020 01:48:40

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-09T21:48:31', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '59a72512-c575-452f-99a9-825f5d5ea908' User entered 'No (N)'	System	10 Aug 2020 01:48:40
	System	10 Aug 2020 01:48:40

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-09T21:48:33', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '59a72512-c575-452f-99a9-825f5d5ea908' User entered 'None (1)'	System	10 Aug 2020 01:48:40
	System	10 Aug 2020 01:48:40

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-09T21:48:39', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '59a72512-c575-452f-99a9-825f5d5ea908' User entered '09 Aug 2020 21:48'	System	10 Aug 2020 01:48:40
	System	10 Aug 2020 01:48:40

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 7'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-10T23:18:24', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '15a581a1-9d08-4122-a9d3-fd3fc9070907' User entered 'None (1)'	System	11 Aug 2020 03:18:46
	System	11 Aug 2020 03:18:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-10T23:18:29', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '15a581a1-9d08-4122-a9d3-fd3fc9070907' User entered 'No (N)'	System	11 Aug 2020 03:18:46
	System	11 Aug 2020 03:18:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-10T23:18:31', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '15a581a1-9d08-4122-a9d3-fd3fc9070907' User entered 'No (N)'	System	11 Aug 2020 03:18:46
	System	11 Aug 2020 03:18:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-10T23:18:34', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '15a581a1-9d08-4122-a9d3-fd3fc9070907' User entered 'None (1)'	System	11 Aug 2020 03:18:46
	System	11 Aug 2020 03:18:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-10T23:18:41', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '15a581a1-9d08-4122-a9d3-fd3fc9070907' User entered '10 Aug 2020 23:18'	System	11 Aug 2020 03:18:46
	System	11 Aug 2020 03:18:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T10:49:26', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f973c9f1-83a7-40fc-8ecc-8dda95e7df97'	System	04 Aug 2020 14:50:02
User entered 'None (0)'	System	04 Aug 2020 14:50:02

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T10:49:29', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f973c9f1-83a7-40fc-8ecc-8dda95e7df97'	System	04 Aug 2020 14:50:02
User entered 'None (0)'	System	04 Aug 2020 14:50:02

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T10:49:31', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f973c9f1-83a7-40fc-8ecc-8dda95e7df97' User entered 'None (0)'	System	04 Aug 2020 14:50:02
	System	04 Aug 2020 14:50:02

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T10:49:34', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f973c9f1-83a7-40fc-8ecc-8dda95e7df97' User entered 'None (0)'	System	04 Aug 2020 14:50:02
	System	04 Aug 2020 14:50:02

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T10:49:37', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f973c9f1-83a7-40fc-8ecc-8dda95e7df97' User entered 'None (0)'	System	04 Aug 2020 14:50:02
	System	04 Aug 2020 14:50:02

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T10:49:40', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f973c9f1-83a7-40fc-8ecc-8dda95e7df97' User entered 'None (0)'	System	04 Aug 2020 14:50:02
	System	04 Aug 2020 14:50:02

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T10:49:50', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f973c9f1-83a7-40fc-8ecc-8dda95e7df97'	System	04 Aug 2020 14:50:02
User entered 'No (N)'	System	04 Aug 2020 14:50:02

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T10:49:57', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f973c9f1-83a7-40fc-8ecc-8dda95e7df97'	System	04 Aug 2020 14:50:02
User entered '04 Aug 2020 10:49'	System	04 Aug 2020 14:50:02

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '04 Aug 2020 10:35'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '04 Aug 2020 13:05'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T20:35:26', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9a1426cb-6aaf-445e-8919-828d2f8c39d9' User entered 'None (0)'	System	05 Aug 2020 00:36:03
	System	05 Aug 2020 00:36:03

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T20:35:32', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9a1426cb-6aaf-445e-8919-828d2f8c39d9' User entered 'None (0)'	System	05 Aug 2020 00:36:03
	System	05 Aug 2020 00:36:03

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T20:35:35', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9a1426cb-6aaf-445e-8919-828d2f8c39d9' User entered 'None (0)'	System	05 Aug 2020 00:36:03
	System	05 Aug 2020 00:36:03

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T20:35:38', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9a1426cb-6aaf-445e-8919-828d2f8c39d9' User entered 'None (0)'	System	05 Aug 2020 00:36:03
	System	05 Aug 2020 00:36:03

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T20:35:40', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9a1426cb-6aaf-445e-8919-828d2f8c39d9' User entered 'None (0)'	System	05 Aug 2020 00:36:03
	System	05 Aug 2020 00:36:03

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T20:35:42', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9a1426cb-6aaf-445e-8919-828d2f8c39d9' User entered 'None (0)'	System	05 Aug 2020 00:36:03
	System	05 Aug 2020 00:36:03

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T20:35:46', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9a1426cb-6aaf-445e-8919-828d2f8c39d9' User entered 'No (N)'	System	05 Aug 2020 00:36:03
	System	05 Aug 2020 00:36:03

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-04T20:36:02', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9a1426cb-6aaf-445e-8919-828d2f8c39d9' User entered '04 Aug 2020 20:36'	System	05 Aug 2020 00:36:03
	System	05 Aug 2020 00:36:03

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '04 Aug 2020 14:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 2'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-05T21:48:49', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '058ca0cd-f71a-4343-9c3f-0147f24ebfc6' User entered 'None (0)'	System	06 Aug 2020 01:49:12
	System	06 Aug 2020 01:49:12

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-05T21:48:52', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '058ca0cd-f71a-4343-9c3f-0147f24ebfc6' User entered 'None (0)'	System	06 Aug 2020 01:49:12
	System	06 Aug 2020 01:49:12

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-05T21:48:54', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '058ca0cd-f71a-4343-9c3f-0147f24ebfc6' User entered 'None (0)'	System	06 Aug 2020 01:49:12
	System	06 Aug 2020 01:49:12

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-05T21:48:56', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '058ca0cd-f71a-4343-9c3f-0147f24ebfc6' User entered 'None (0)'	System	06 Aug 2020 01:49:12
	System	06 Aug 2020 01:49:12

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-05T21:48:59', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '058ca0cd-f71a-4343-9c3f-0147f24ebfc6' User entered 'None (0)'	System	06 Aug 2020 01:49:12
	System	06 Aug 2020 01:49:12

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-05T21:49:01', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '058ca0cd-f71a-4343-9c3f-0147f24ebfc6' User entered 'None (0)'	System	06 Aug 2020 01:49:12
	System	06 Aug 2020 01:49:12

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-05T21:49:04', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '058ca0cd-f71a-4343-9c3f-0147f24ebfc6' User entered 'No (N)'	System	06 Aug 2020 01:49:12

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-05T21:49:11', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '058ca0cd-f71a-4343-9c3f-0147f24ebfc6' User entered '05 Aug 2020 21:49'	System	06 Aug 2020 01:49:12
	System	06 Aug 2020 01:49:12

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 3'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-06T21:48:32', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '1f49bbb3-c4f3-4b35-9f22-6de00b40dcab' User entered 'None (0)'	System	07 Aug 2020 01:48:57
	System	07 Aug 2020 01:48:57

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-06T21:48:35', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '1f49bbb3-c4f3-4b35-9f22-6de00b40dcab' User entered 'None (0)'	System	07 Aug 2020 01:48:57
	System	07 Aug 2020 01:48:57

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-06T21:48:38', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '1f49bbb3-c4f3-4b35-9f22-6de00b40dcab' User entered 'None (0)'	System	07 Aug 2020 01:48:57
	System	07 Aug 2020 01:48:57

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-06T21:48:39', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '1f49bbb3-c4f3-4b35-9f22-6de00b40dcab' User entered 'None (0)'	System	07 Aug 2020 01:48:57
	System	07 Aug 2020 01:48:57

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-06T21:48:41', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '1f49bbb3-c4f3-4b35-9f22-6de00b40dcab' User entered 'None (0)'	System	07 Aug 2020 01:48:57
	System	07 Aug 2020 01:48:57

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-06T21:48:44', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '1f49bbb3-c4f3-4b35-9f22-6de00b40dcab' User entered 'None (0)'	System	07 Aug 2020 01:48:57
	System	07 Aug 2020 01:48:57

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-06T21:48:46', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '1f49bbb3-c4f3-4b35-9f22-6de00b40dcab' User entered 'No (N)'	System	07 Aug 2020 01:48:57
	System	07 Aug 2020 01:48:57

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-06T21:48:54', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '1f49bbb3-c4f3-4b35-9f22-6de00b40dcab' User entered '06 Aug 2020 21:48'	System	07 Aug 2020 01:48:57
	System	07 Aug 2020 01:48:57

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 4'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-07T22:09:37', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e6a0975c-fe9a-4fcf-ae1f-a5eee12d27c2'	System	08 Aug 2020 02:09:59
User entered 'None (0)'	System	08 Aug 2020 02:09:59

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-07T22:09:39', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e6a0975c-fe9a-4fcf-ae1f-a5eee12d27c2'	System	08 Aug 2020 02:09:59
User entered 'None (0)'	System	08 Aug 2020 02:09:59

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-07T22:09:42', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e6a0975c-fe9a-4fcf-ae1f-a5eee12d27c2'	System	08 Aug 2020 02:09:59
User entered 'None (0)'	System	08 Aug 2020 02:09:59

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-07T22:09:45', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e6a0975c-fe9a-4fcf-ae1f-a5eee12d27c2' User entered 'None (0)'	System	08 Aug 2020 02:09:59
	System	08 Aug 2020 02:09:59

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-07T22:09:47', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e6a0975c-fe9a-4fcf-ae1f-a5eee12d27c2'	System	08 Aug 2020 02:09:59
User entered 'None (0)'	System	08 Aug 2020 02:09:59

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-07T22:09:49', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e6a0975c-fe9a-4fcf-ae1f-a5eee12d27c2'	System	08 Aug 2020 02:09:59
User entered 'None (0)'	System	08 Aug 2020 02:09:59

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-07T22:09:51', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e6a0975c-fe9a-4fcf-ae1f-a5eee12d27c2'	System	08 Aug 2020 02:09:59
User entered 'No (N)'	System	08 Aug 2020 02:09:59

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-07T22:09:56', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e6a0975c-fe9a-4fcf-ae1f-a5eee12d27c2'	System	08 Aug 2020 02:09:59
User entered '07 Aug 2020 22:09'	System	08 Aug 2020 02:09:59

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 5'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-08T22:35:39', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '59c6cf5f-141c-47b0-a0e7-743c5bad2db1' User entered 'None (0)'	System	09 Aug 2020 02:36:05
	System	09 Aug 2020 02:36:05

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-08T22:35:41', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '59c6cf5f-141c-47b0-a0e7-743c5bad2db1' User entered 'None (0)'	System	09 Aug 2020 02:36:05
	System	09 Aug 2020 02:36:05

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-08T22:35:43', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '59c6cf5f-141c-47b0-a0e7-743c5bad2db1' User entered 'None (0)'	System	09 Aug 2020 02:36:05
	System	09 Aug 2020 02:36:05

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-08T22:35:45', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '59c6cf5f-141c-47b0-a0e7-743c5bad2db1' User entered 'None (0)'	System	09 Aug 2020 02:36:05
	System	09 Aug 2020 02:36:05

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-08T22:35:48', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '59c6cf5f-141c-47b0-a0e7-743c5bad2db1' User entered 'None (0)'	System	09 Aug 2020 02:36:05
	System	09 Aug 2020 02:36:05

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-08T22:35:50', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '59c6cf5f-141c-47b0-a0e7-743c5bad2db1' User entered 'None (0)'	System	09 Aug 2020 02:36:05
	System	09 Aug 2020 02:36:05

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-08T22:35:52', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '59c6cf5f-141c-47b0-a0e7-743c5bad2db1' User entered 'No (N)'	System	09 Aug 2020 02:36:05
	System	09 Aug 2020 02:36:05

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-08T22:35:59', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '59c6cf5f-141c-47b0-a0e7-743c5bad2db1' User entered '08 Aug 2020 22:35'	System	09 Aug 2020 02:36:05
	System	09 Aug 2020 02:36:05

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 6'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-09T21:48:42', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'be702ce0-8765-42cb-b312-ec588417eee8' User entered 'None (0)'	System	10 Aug 2020 01:49:10
	System	10 Aug 2020 01:49:10

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-09T21:48:47', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'be702ce0-8765-42cb-b312-ec588417eee8' User entered 'None (0)'	System	10 Aug 2020 01:49:10
	System	10 Aug 2020 01:49:10

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-09T21:48:51', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'be702ce0-8765-42cb-b312-ec588417eee8' User entered 'None (0)'	System	10 Aug 2020 01:49:10
	System	10 Aug 2020 01:49:10

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-09T21:48:54', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'be702ce0-8765-42cb-b312-ec588417eee8' User entered 'None (0)'	System	10 Aug 2020 01:49:10
	System	10 Aug 2020 01:49:10

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-09T21:48:57', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'be702ce0-8765-42cb-b312-ec588417eee8' User entered 'None (0)'	System	10 Aug 2020 01:49:10
	System	10 Aug 2020 01:49:10

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-09T21:48:59', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'be702ce0-8765-42cb-b312-ec588417eee8' User entered 'None (0)'	System	10 Aug 2020 01:49:10
	System	10 Aug 2020 01:49:10

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-09T21:49:02', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'be702ce0-8765-42cb-b312-ec588417eee8' User entered 'No (N)'	System	10 Aug 2020 01:49:10
	System	10 Aug 2020 01:49:10

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-09T21:49:09', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'be702ce0-8765-42cb-b312-ec588417eee8' User entered '09 Aug 2020 21:49'	System	10 Aug 2020 01:49:10
	System	10 Aug 2020 01:49:10

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 7'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-10T23:18:45', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '8e80c1a3-8e82-46f4-b03c-fba76e98d99a' User entered 'None (0)'	System	11 Aug 2020 03:19:10
	System	11 Aug 2020 03:19:10

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-10T23:18:51', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '8e80c1a3-8e82-46f4-b03c-fba76e98d99a' User entered 'None (0)'	System	11 Aug 2020 03:19:10
	System	11 Aug 2020 03:19:10

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-10T23:18:53', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '8e80c1a3-8e82-46f4-b03c-fba76e98d99a' User entered 'None (0)'	System	11 Aug 2020 03:19:10
	System	11 Aug 2020 03:19:10

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-10T23:18:55', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '8e80c1a3-8e82-46f4-b03c-fba76e98d99a' User entered 'None (0)'	System	11 Aug 2020 03:19:10
	System	11 Aug 2020 03:19:10

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-10T23:18:57', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '8e80c1a3-8e82-46f4-b03c-fba76e98d99a' User entered 'None (0)'	System	11 Aug 2020 03:19:10
	System	11 Aug 2020 03:19:10

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-10T23:18:59', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '8e80c1a3-8e82-46f4-b03c-fba76e98d99a' User entered 'None (0)'	System	11 Aug 2020 03:19:10
	System	11 Aug 2020 03:19:10

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-10T23:19:02', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '8e80c1a3-8e82-46f4-b03c-fba76e98d99a' User entered 'No (N)'	System	11 Aug 2020 03:19:10
	System	11 Aug 2020 03:19:10

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-08-10T23:19:09', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '8e80c1a3-8e82-46f4-b03c-fba76e98d99a' User entered '10 Aug 2020 23:19'	System	11 Aug 2020 03:19:10
	System	11 Aug 2020 03:19:10

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 14:29:46

US3402211

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	11 Aug 2020 17:35:10

US3402211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '11 Aug 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	11 Aug 2020 17:35:10

US3402211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	11 Aug 2020 17:35:10

US3402211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	Traci Hull (b) (4)	11 Aug 2020 17:35:10

US3402211

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	11 Aug 2020 17:35:16

US3402211

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'I'	System	11 Aug 2020 17:35:16

US3402211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	19 Aug 2020 12:24:21

US3402211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '18 Aug 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Aug 2020 12:24:21

US3402211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Aug 2020 12:24:21

US3402211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	19 Aug 2020 12:24:21
	(b) (4)	

US3402211

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Aug 2020 12:24:27

US3402211

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'I'	System	19 Aug 2020 12:24:27

US3402211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	26 Aug 2020 13:08:29

US3402211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '25 Aug 2020'	Traci Hull (b) (4)	26 Aug 2020 13:08:29

US3402211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	26 Aug 2020 13:08:29

US3402211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	Traci Hull (b) (4)	26 Aug 2020 13:08:29

US3402211

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	26 Aug 2020 13:08:35

US3402211

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'I'	System	26 Aug 2020 13:08:35

US3402211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	01 Sep 2020 13:30:09

US3402211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '1 Sep 2020'	Jennifer Molstead (b) (4)	01 Sep 2020 13:30:09

US3402211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4)	01 Sep 2020 13:30:09

US3402211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'VISIT2'	System	01 Sep 2020 13:30:09

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '1 Sep 2020'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '08:31'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered '1 Sep 2020 08:31'	System	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '98.2' F	Traci Hull (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	01 Sep 2020 19:32:05
	(b) (4)	

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '51'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'bpm'	System	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '14'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'breaths/min'	System	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '118'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'mmHg'	System	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '75'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'mmHg'	System	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '1 Sep 2020'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '09:32'	Traci Hull (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered '1 Sep 2020 09:32'	System	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '98.3' F	Traci Hull (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '48'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'bpm'	System	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '14'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'breaths/min'	System	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '112'	(b) (4)	
	Traci Hull (b) (4)	01 Sep 2020 19:32:05
	(b) (4)	

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'mmHg'	System	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '67'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'mmHg'	System	01 Sep 2020 19:32:05

US3402211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4)	01 Sep 2020 19:32:11
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '1 Sep 2020'	(b) (4)	
	Traci Hull (b) (4)	01 Sep 2020 19:32:11
	(b) (4)	

US3402211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	01 Sep 2020 13:30:31

US3402211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	Jennifer Molstead (b) (4)	01 Sep 2020 13:30:31

US3402211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	Jennifer Molstead (b) (4)	01 Sep 2020 13:30:31

US3402211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 13:30:31

US3402211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '1 Sep 2020'	Jennifer Molstead (b) (4)	01 Sep 2020 13:30:31

US3402211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '08:58'	Jennifer Molstead (b) (4)	01 Sep 2020 13:30:31

US3402211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered '1 Sep 2020 08:58'	System	01 Sep 2020 13:30:31

US3402211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4)	01 Sep 2020 13:30:31

US3402211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'ONCE'	System	01 Sep 2020 13:30:31

US3402211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 13:30:31

US3402211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 19:32:30

US3402211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '1 Sep 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 19:32:30

US3402211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '08:46'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 19:32:30

US3402211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered '1 Sep 2020 08:46'	System	01 Sep 2020 19:32:30

US3402211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:30:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '1 Sep 2020'	Traci Hull (b) (4)	01 Sep 2020 19:32:43

US3402211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:30:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 19:32:43

US3402211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:30:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 19:32:43

US3402211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:30:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '08:45'	(b) (4)	
	Traci Hull (b) (4)	01 Sep 2020 19:32:43
	(b) (4)	

US3402211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:30:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered '1 Sep 2020 08:45'	System	01 Sep 2020 19:32:43

US3402211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 19:32:43

US3402211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 19:32:43

US3402211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	01 Sep 2020 19:32:43

US3402211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:30:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered empty.	System	01 Sep 2020 19:32:43

US3402211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	01 Sep 2020 19:32:48

US3402211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered '1'	System	01 Sep 2020 19:32:48

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T09:34:53', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '5da68d03-949b-4d77-a9f1-63e48b5cbea1' User entered 'Yes (Y)'	System	01 Sep 2020 13:35:12
	System	01 Sep 2020 13:35:12

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T09:34:59', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '5da68d03-949b-4d77-a9f1-63e48b5cbea1' User entered '99.3'	System	01 Sep 2020 13:35:12
	System	01 Sep 2020 13:35:12

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T09:35:03', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '5da68d03-949b-4d77-a9f1-63e48b5cbea1' User entered 'No (N)'	System	01 Sep 2020 13:35:12
	System	01 Sep 2020 13:35:12

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T09:35:10', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '5da68d03-949b-4d77-a9f1-63e48b5cbea1' User entered '01 Sep 2020 09:35'	System	01 Sep 2020 13:35:12
	System	01 Sep 2020 13:35:12

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '01 Sep 2020 09:18'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '01 Sep 2020 11:48'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T21:38:55', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '31f6ba9a-89a7-4275-a75b-16d5eb33f6c8' User entered 'Yes (Y)'	System	02 Sep 2020 01:39:09
	System	02 Sep 2020 01:39:09

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T21:39:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '31f6ba9a-89a7-4275-a75b-16d5eb33f6c8' User entered '97.5'	System	02 Sep 2020 01:39:09
	System	02 Sep 2020 01:39:09

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T21:39:02', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '31f6ba9a-89a7-4275-a75b-16d5eb33f6c8' User entered 'No (N)'	System	02 Sep 2020 01:39:09
	System	02 Sep 2020 01:39:09

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T21:39:06', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '31f6ba9a-89a7-4275-a75b-16d5eb33f6c8' User entered '01 Sep 2020 21:39'	System	02 Sep 2020 01:39:09
	System	02 Sep 2020 01:39:09

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '01 Sep 2020 12:43'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 2'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:30

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-02T22:02:46', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '50b23fc5-636f-42e8-bab7-6e2e1550d683' User entered 'Yes (Y)'	System	03 Sep 2020 02:03:08
	System	03 Sep 2020 02:03:08

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-02T22:02:53', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '50b23fc5-636f-42e8-bab7-6e2e1550d683' User entered '98.1'	System	03 Sep 2020 02:03:08
	System	03 Sep 2020 02:03:08

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-02T22:02:55', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '50b23fc5-636f-42e8-bab7-6e2e1550d683'	System	03 Sep 2020 02:03:08
User entered 'No (N)'	System	03 Sep 2020 02:03:08

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-02T22:03:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '50b23fc5-636f-42e8-bab7-6e2e1550d683' User entered '02 Sep 2020 22:03'	System	03 Sep 2020 02:03:08
	System	03 Sep 2020 02:03:08

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 3'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-03T21:08:42', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '580ff957-d8ba-41bd-b206-98eda81b6772'	System	04 Sep 2020 01:09:01
User entered 'Yes (Y)'	System	04 Sep 2020 01:09:01

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-03T21:08:49', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '580ff957-d8ba-41bd-b206-98eda81b6772' User entered '98.1'	System	04 Sep 2020 01:09:01
	System	04 Sep 2020 01:09:01

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-03T21:08:52', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '580ff957-d8ba-41bd-b206-98eda81b6772'	System	04 Sep 2020 01:09:01
User entered 'No (N)'	System	04 Sep 2020 01:09:01

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-03T21:08:56', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '580ff957-d8ba-41bd-b206-98eda81b6772' User entered '03 Sep 2020 21:08'	System	04 Sep 2020 01:09:01
	System	04 Sep 2020 01:09:01

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 4'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:30

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 5'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-05T22:54:08', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '6c1d2c1b-781f-4091-94d3-c364942fe0dc' User entered 'Yes (Y)'	System	06 Sep 2020 02:54:29
	System	06 Sep 2020 02:54:29

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-05T22:54:20', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '6c1d2c1b-781f-4091-94d3-c364942fe0dc' User entered '98.2'	System	06 Sep 2020 02:54:29
	System	06 Sep 2020 02:54:29

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-05T22:54:23', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '6c1d2c1b-781f-4091-94d3-c364942fe0dc' User entered 'No (N)'	System	06 Sep 2020 02:54:29

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-05T22:54:26', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '6c1d2c1b-781f-4091-94d3-c364942fe0dc' User entered '05 Sep 2020 22:54'	System	06 Sep 2020 02:54:29
	System	06 Sep 2020 02:54:29

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 6'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-06T23:25:32', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '41ba1977-9aae-43b0-8f7f-79de81399d2c' User entered 'Yes (Y)'	System	07 Sep 2020 03:25:48
	System	07 Sep 2020 03:25:48

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-06T23:25:38', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '41ba1977-9aae-43b0-8f7f-79de81399d2c' User entered '96.5'	System	07 Sep 2020 03:25:48
	System	07 Sep 2020 03:25:48

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-06T23:25:41', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '41ba1977-9aae-43b0-8f7f-79de81399d2c' User entered 'No (N)'	System	07 Sep 2020 03:25:48
	System	07 Sep 2020 03:25:48

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-06T23:25:45', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '41ba1977-9aae-43b0-8f7f-79de81399d2c' User entered '06 Sep 2020 23:25'	System	07 Sep 2020 03:25:48
	System	07 Sep 2020 03:25:48

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 7'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-07T22:25:49', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9fd1792e-ba60-44e4-9a8d-fb1270aaad77' User entered 'Yes (Y)'	System	08 Sep 2020 02:26:01
	System	08 Sep 2020 02:26:01

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-07T22:25:53', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9fd1792e-ba60-44e4-9a8d-fb1270aaad77' User entered '98.3'	System	08 Sep 2020 02:26:01
	System	08 Sep 2020 02:26:01

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:30

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-07T22:25:56', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9fd1792e-ba60-44e4-9a8d-fb1270aaad77'	System	08 Sep 2020 02:26:01
User entered 'No (N)'	System	08 Sep 2020 02:26:01

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-07T22:26:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9fd1792e-ba60-44e4-9a8d-fb1270aaad77' User entered '07 Sep 2020 22:26'	System	08 Sep 2020 02:26:01
	System	08 Sep 2020 02:26:01

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T09:35:21', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '29902040-f4f7-4f56-b1eb-f79f03236756'	System	01 Sep 2020 13:35:46
User entered 'None (1)'	System	01 Sep 2020 13:35:46

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T09:35:26', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '29902040-f4f7-4f56-b1eb-f79f03236756' User entered 'No (N)'	System	01 Sep 2020 13:35:46
	System	01 Sep 2020 13:35:46

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T09:35:33', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '29902040-f4f7-4f56-b1eb-f79f03236756'	System	01 Sep 2020 13:35:46
User entered 'No (N)'	System	01 Sep 2020 13:35:46

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T09:35:38', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '29902040-f4f7-4f56-b1eb-f79f03236756' User entered 'None (1)'	System	01 Sep 2020 13:35:46
	System	01 Sep 2020 13:35:46

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T09:35:43', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '29902040-f4f7-4f56-b1eb-f79f03236756'	System	01 Sep 2020 13:35:46
User entered '01 Sep 2020 09:35'	System	01 Sep 2020 13:35:46

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '01 Sep 2020 09:18'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '01 Sep 2020 11:48'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T21:39:11', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ba9a6c2f-8c88-4c26-b964-7e6a120707bf' User entered 'None (1)'	System	02 Sep 2020 01:39:26
	System	02 Sep 2020 01:39:26

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T21:39:14', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ba9a6c2f-8c88-4c26-b964-7e6a120707bf' User entered 'No (N)'	System	02 Sep 2020 01:39:26
	System	02 Sep 2020 01:39:26

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T21:39:16', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ba9a6c2f-8c88-4c26-b964-7e6a120707bf' User entered 'No (N)'	System	02 Sep 2020 01:39:26
	System	02 Sep 2020 01:39:26

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T21:39:18', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ba9a6c2f-8c88-4c26-b964-7e6a120707bf' User entered 'None (1)'	System	02 Sep 2020 01:39:26
	System	02 Sep 2020 01:39:26

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T21:39:22', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ba9a6c2f-8c88-4c26-b964-7e6a120707bf' User entered '01 Sep 2020 21:39'	System	02 Sep 2020 01:39:26
	System	02 Sep 2020 01:39:26

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '01 Sep 2020 12:43'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 2'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-02T22:03:05', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3cf681ad-1b69-4d3b-8a06-0edb5248c345' User entered 'None (1)'	System	03 Sep 2020 02:03:34
	System	03 Sep 2020 02:03:34

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-02T22:03:08', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3cf681ad-1b69-4d3b-8a06-0edb5248c345' User entered 'No (N)'	System	03 Sep 2020 02:03:34
	System	03 Sep 2020 02:03:34

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-02T22:03:11', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3cf681ad-1b69-4d3b-8a06-0edb5248c345' User entered 'No (N)'	System	03 Sep 2020 02:03:34
	System	03 Sep 2020 02:03:34

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-02T22:03:24', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3cf681ad-1b69-4d3b-8a06-0edb5248c345' User entered 'None (1)'	System	03 Sep 2020 02:03:34
	System	03 Sep 2020 02:03:34

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-02T22:03:29', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3cf681ad-1b69-4d3b-8a06-0edb5248c345' User entered '02 Sep 2020 22:03'	System	03 Sep 2020 02:03:34
	System	03 Sep 2020 02:03:34

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 3'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-03T21:09:27', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '0d068cd5-4d59-4442-8b15-ecbd42732ef2' User entered 'None (1)'	System	04 Sep 2020 01:09:45
	System	04 Sep 2020 01:09:45

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-03T21:09:26', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '0d068cd5-4d59-4442-8b15-ecbd42732ef2' User entered 'No (N)'	System	04 Sep 2020 01:09:45
	System	04 Sep 2020 01:09:45

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-03T21:09:29', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '0d068cd5-4d59-4442-8b15-ecbd42732ef2' User entered 'No (N)'	System	04 Sep 2020 01:09:45
	System	04 Sep 2020 01:09:45

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-03T21:09:37', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '0d068cd5-4d59-4442-8b15-ecbd42732ef2' User entered 'None (1)'	System	04 Sep 2020 01:09:45
	System	04 Sep 2020 01:09:45

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-03T21:09:43', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '0d068cd5-4d59-4442-8b15-ecbd42732ef2' User entered '03 Sep 2020 21:09'	System	04 Sep 2020 01:09:45
	System	04 Sep 2020 01:09:45

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 4'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 5'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-05T22:54:31', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '4b380e3b-aca5-4e99-8648-1e3960395307' User entered 'None (1)'	System	06 Sep 2020 02:54:46
	System	06 Sep 2020 02:54:46

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-05T22:54:33', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '4b380e3b-aca5-4e99-8648-1e3960395307' User entered 'No (N)'	System	06 Sep 2020 02:54:46
	System	06 Sep 2020 02:54:46

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-05T22:54:35', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '4b380e3b-aca5-4e99-8648-1e3960395307' User entered 'No (N)'	System	06 Sep 2020 02:54:46

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-05T22:54:38', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '4b380e3b-aca5-4e99-8648-1e3960395307' User entered 'None (1)'	System	06 Sep 2020 02:54:46
	System	06 Sep 2020 02:54:46

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-05T22:54:43', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '4b380e3b-aca5-4e99-8648-1e3960395307' User entered '05 Sep 2020 22:54'	System	06 Sep 2020 02:54:46
	System	06 Sep 2020 02:54:46

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 6'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-06T23:25:50', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ae019d2b-4a16-4e70-9d9b-06a6bff355bd' User entered 'None (1)'	System	07 Sep 2020 03:26:09
	System	07 Sep 2020 03:26:09

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-06T23:25:52', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ae019d2b-4a16-4e70-9d9b-06a6bff355bd' User entered 'No (N)'	System	07 Sep 2020 03:26:09
	System	07 Sep 2020 03:26:09

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-06T23:25:54', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ae019d2b-4a16-4e70-9d9b-06a6bff355bd' User entered 'No (N)'	System	07 Sep 2020 03:26:09
	System	07 Sep 2020 03:26:09

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-06T23:26:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ae019d2b-4a16-4e70-9d9b-06a6bff355bd' User entered 'None (1)'	System	07 Sep 2020 03:26:09
	System	07 Sep 2020 03:26:09

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-06T23:26:06', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ae019d2b-4a16-4e70-9d9b-06a6bff355bd' User entered '06 Sep 2020 23:26'	System	07 Sep 2020 03:26:09
	System	07 Sep 2020 03:26:09

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 7'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:30

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-07T22:26:04', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '880daf9c-6862-4738-962b-308b2c349e42'	System	08 Sep 2020 02:26:19
User entered 'None (1)'	System	08 Sep 2020 02:26:19

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-07T22:26:07', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '880daf9c-6862-4738-962b-308b2c349e42' User entered 'No (N)'	System	08 Sep 2020 02:26:19
	System	08 Sep 2020 02:26:19

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:30

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-07T22:26:09', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '880daf9c-6862-4738-962b-308b2c349e42'	System	08 Sep 2020 02:26:19
User entered 'No (N)'	System	08 Sep 2020 02:26:19

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:30

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-07T22:26:11', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '880daf9c-6862-4738-962b-308b2c349e42'	System	08 Sep 2020 02:26:19
User entered 'None (1)'	System	08 Sep 2020 02:26:19

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-07T22:26:17', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '880daf9c-6862-4738-962b-308b2c349e42' User entered '07 Sep 2020 22:26'	System	08 Sep 2020 02:26:19
	System	08 Sep 2020 02:26:19

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T09:35:47', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '567ae18b-9d9b-4bc1-8357-760b5cf326f5' User entered 'None (0)'	System	01 Sep 2020 13:36:10
	System	01 Sep 2020 13:36:10

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T09:35:49', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '567ae18b-9d9b-4bc1-8357-760b5cf326f5' User entered 'None (0)'	System	01 Sep 2020 13:36:10
	System	01 Sep 2020 13:36:10

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T09:35:51', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '567ae18b-9d9b-4bc1-8357-760b5cf326f5' User entered 'None (0)'	System	01 Sep 2020 13:36:10
	System	01 Sep 2020 13:36:10

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T09:35:53', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '567ae18b-9d9b-4bc1-8357-760b5cf326f5' User entered 'None (0)'	System	01 Sep 2020 13:36:10
	System	01 Sep 2020 13:36:10

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T09:35:55', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '567ae18b-9d9b-4bc1-8357-760b5cf326f5' User entered 'None (0)'	System	01 Sep 2020 13:36:10
	System	01 Sep 2020 13:36:10

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T09:35:57', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '567ae18b-9d9b-4bc1-8357-760b5cf326f5' User entered 'None (0)'	System	01 Sep 2020 13:36:10
	System	01 Sep 2020 13:36:10

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T09:35:59', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '567ae18b-9d9b-4bc1-8357-760b5cf326f5' User entered 'No (N)'	System	01 Sep 2020 13:36:10
	System	01 Sep 2020 13:36:10

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T09:36:07', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '567ae18b-9d9b-4bc1-8357-760b5cf326f5' User entered '01 Sep 2020 09:36'	System	01 Sep 2020 13:36:10
	System	01 Sep 2020 13:36:10

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '01 Sep 2020 09:18'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '01 Sep 2020 11:48'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T21:39:27', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f84bb377-9aff-44f8-b1bc-80ff9fd4989b' User entered 'None (0)'	System	02 Sep 2020 01:39:50
	System	02 Sep 2020 01:39:50

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T21:39:29', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f84bb377-9aff-44f8-b1bc-80ff9fd4989b' User entered 'None (0)'	System	02 Sep 2020 01:39:50
	System	02 Sep 2020 01:39:50

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T21:39:31', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f84bb377-9aff-44f8-b1bc-80ff9fd4989b' User entered 'None (0)'	System	02 Sep 2020 01:39:50
	System	02 Sep 2020 01:39:50

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T21:39:33', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f84bb377-9aff-44f8-b1bc-80ff9fd4989b' User entered 'None (0)'	System	02 Sep 2020 01:39:50
	System	02 Sep 2020 01:39:50

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T21:39:35', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f84bb377-9aff-44f8-b1bc-80ff9fd4989b' User entered 'None (0)'	System	02 Sep 2020 01:39:50
	System	02 Sep 2020 01:39:50

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T21:39:38', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f84bb377-9aff-44f8-b1bc-80ff9fd4989b' User entered 'None (0)'	System	02 Sep 2020 01:39:50
	System	02 Sep 2020 01:39:50

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T21:39:40', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f84bb377-9aff-44f8-b1bc-80ff9fd4989b'	System	02 Sep 2020 01:39:50
User entered 'No (N)'	System	02 Sep 2020 01:39:50

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-01T21:39:46', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f84bb377-9aff-44f8-b1bc-80ff9fd4989b'	System	02 Sep 2020 01:39:50
User entered '01 Sep 2020 21:39'	System	02 Sep 2020 01:39:50

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '01 Sep 2020 12:43'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 2'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-02T22:03:33', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ab5458e5-1e49-4f08-851f-89cbd0399ce0' User entered 'None (0)'	System	03 Sep 2020 02:04:00
	System	03 Sep 2020 02:04:00

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-02T22:03:35', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ab5458e5-1e49-4f08-851f-89cbd0399ce0' User entered 'None (0)'	System	03 Sep 2020 02:04:00
	System	03 Sep 2020 02:04:00

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-02T22:03:37', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ab5458e5-1e49-4f08-851f-89cbd0399ce0' User entered 'None (0)'	System	03 Sep 2020 02:04:00
	System	03 Sep 2020 02:04:00

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-02T22:03:39', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ab5458e5-1e49-4f08-851f-89cbd0399ce0' User entered 'None (0)'	System	03 Sep 2020 02:04:00
	System	03 Sep 2020 02:04:00

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-02T22:03:41', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ab5458e5-1e49-4f08-851f-89cbd0399ce0' User entered 'None (0)'	System	03 Sep 2020 02:04:00
	System	03 Sep 2020 02:04:00

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-02T22:03:43', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ab5458e5-1e49-4f08-851f-89cbd0399ce0' User entered 'None (0)'	System	03 Sep 2020 02:04:00
	System	03 Sep 2020 02:04:00

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-02T22:03:46', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ab5458e5-1e49-4f08-851f-89cbd0399ce0' User entered 'No (N)'	System	03 Sep 2020 02:04:00
	System	03 Sep 2020 02:04:00

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-02T22:03:58', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ab5458e5-1e49-4f08-851f-89cbd0399ce0' User entered '02 Sep 2020 22:03'	System	03 Sep 2020 02:04:00
	System	03 Sep 2020 02:04:00

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 3'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-03T21:09:47', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3087cdfc-6298-48de-a1f7-c4775c2c6e51' User entered 'None (0)'	System	04 Sep 2020 01:10:12
	System	04 Sep 2020 01:10:12

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-03T21:09:49', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3087cdfc-6298-48de-a1f7-c4775c2c6e51' User entered 'None (0)'	System	04 Sep 2020 01:10:12
	System	04 Sep 2020 01:10:12

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-03T21:09:51', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3087cdfc-6298-48de-a1f7-c4775c2c6e51' User entered 'None (0)'	System	04 Sep 2020 01:10:12
	System	04 Sep 2020 01:10:12

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-03T21:09:53', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3087cdfc-6298-48de-a1f7-c4775c2c6e51' User entered 'None (0)'	System	04 Sep 2020 01:10:12
	System	04 Sep 2020 01:10:12

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-03T21:09:55', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3087cdfc-6298-48de-a1f7-c4775c2c6e51' User entered 'None (0)'	System	04 Sep 2020 01:10:12
	System	04 Sep 2020 01:10:12

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-03T21:09:57', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3087cdfc-6298-48de-a1f7-c4775c2c6e51' User entered 'None (0)'	System	04 Sep 2020 01:10:12
	System	04 Sep 2020 01:10:12

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-03T21:10:03', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3087cdfc-6298-48de-a1f7-c4775c2c6e51' User entered 'No (N)'	System	04 Sep 2020 01:10:12
	System	04 Sep 2020 01:10:12

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-03T21:10:10', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3087cdfc-6298-48de-a1f7-c4775c2c6e51' User entered '03 Sep 2020 21:10'	System	04 Sep 2020 01:10:12
	System	04 Sep 2020 01:10:12

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 4'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 5'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-05T22:54:47', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '217a461e-1c82-47e8-b79d-35d96c7b2ae2' User entered 'None (0)'	System	06 Sep 2020 02:55:10
	System	06 Sep 2020 02:55:10

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-05T22:54:50', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '217a461e-1c82-47e8-b79d-35d96c7b2ae2' User entered 'None (0)'	System	06 Sep 2020 02:55:10
	System	06 Sep 2020 02:55:10

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-05T22:54:52', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '217a461e-1c82-47e8-b79d-35d96c7b2ae2' User entered 'None (0)'	System	06 Sep 2020 02:55:10
	System	06 Sep 2020 02:55:10

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-05T22:54:54', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '217a461e-1c82-47e8-b79d-35d96c7b2ae2' User entered 'None (0)'	System	06 Sep 2020 02:55:10
	System	06 Sep 2020 02:55:10

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-05T22:54:57', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '217a461e-1c82-47e8-b79d-35d96c7b2ae2' User entered 'None (0)'	System	06 Sep 2020 02:55:10
	System	06 Sep 2020 02:55:10

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-05T22:54:59', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '217a461e-1c82-47e8-b79d-35d96c7b2ae2' User entered 'None (0)'	System	06 Sep 2020 02:55:10
	System	06 Sep 2020 02:55:10

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-05T22:55:01', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '217a461e-1c82-47e8-b79d-35d96c7b2ae2' User entered 'No (N)'	System	06 Sep 2020 02:55:10
	System	06 Sep 2020 02:55:10

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-05T22:55:08', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '217a461e-1c82-47e8-b79d-35d96c7b2ae2' User entered '05 Sep 2020 22:55'	System	06 Sep 2020 02:55:10
	System	06 Sep 2020 02:55:10

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 6'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-06T23:26:09', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '6bee2035-6791-44c1-a1ea-f5a05e8916be' User entered 'None (0)'	System	07 Sep 2020 03:26:32
	System	07 Sep 2020 03:26:32

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-06T23:26:11', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '6bee2035-6791-44c1-a1ea-f5a05e8916be' User entered 'None (0)'	System	07 Sep 2020 03:26:32
	System	07 Sep 2020 03:26:32

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-06T23:26:13', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '6bee2035-6791-44c1-a1ea-f5a05e8916be' User entered 'None (0)'	System	07 Sep 2020 03:26:32
	System	07 Sep 2020 03:26:32

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-06T23:26:15', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '6bee2035-6791-44c1-a1ea-f5a05e8916be' User entered 'None (0)'	System	07 Sep 2020 03:26:32
	System	07 Sep 2020 03:26:32

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-06T23:26:17', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '6bee2035-6791-44c1-a1ea-f5a05e8916be' User entered 'None (0)'	System	07 Sep 2020 03:26:32
	System	07 Sep 2020 03:26:32

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-06T23:26:19', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '6bee2035-6791-44c1-a1ea-f5a05e8916be' User entered 'None (0)'	System	07 Sep 2020 03:26:32
	System	07 Sep 2020 03:26:32

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-06T23:26:21', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '6bee2035-6791-44c1-a1ea-f5a05e8916be' User entered 'No (N)'	System	07 Sep 2020 03:26:32
	System	07 Sep 2020 03:26:32

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-06T23:26:29', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '6bee2035-6791-44c1-a1ea-f5a05e8916be' User entered '06 Sep 2020 23:26'	System	07 Sep 2020 03:26:32
	System	07 Sep 2020 03:26:32

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	01 Sep 2020 13:30:31
User entered 'Day 7'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-07T22:26:20', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9c2d4086-9b24-4c3c-9bb4-0d778612b49e' User entered 'None (0)'	System	08 Sep 2020 02:26:47
	System	08 Sep 2020 02:26:47

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-07T22:26:22', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9c2d4086-9b24-4c3c-9bb4-0d778612b49e' User entered 'None (0)'	System	08 Sep 2020 02:26:47
	System	08 Sep 2020 02:26:47

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-07T22:26:24', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9c2d4086-9b24-4c3c-9bb4-0d778612b49e' User entered 'None (0)'	System	08 Sep 2020 02:26:47
	System	08 Sep 2020 02:26:47

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-07T22:26:25', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9c2d4086-9b24-4c3c-9bb4-0d778612b49e' User entered 'None (0)'	System	08 Sep 2020 02:26:47
	System	08 Sep 2020 02:26:47

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-07T22:26:28', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9c2d4086-9b24-4c3c-9bb4-0d778612b49e' User entered 'None (0)'	System	08 Sep 2020 02:26:47
	System	08 Sep 2020 02:26:47

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-07T22:26:30', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9c2d4086-9b24-4c3c-9bb4-0d778612b49e' User entered 'None (0)'	System	08 Sep 2020 02:26:47
	System	08 Sep 2020 02:26:47

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-07T22:26:33', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9c2d4086-9b24-4c3c-9bb4-0d778612b49e' User entered 'No (N)'	System	08 Sep 2020 02:26:47
	System	08 Sep 2020 02:26:47

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-09-07T22:26:46', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '9c2d4086-9b24-4c3c-9bb4-0d778612b49e' User entered '07 Sep 2020 22:26'	System	08 Sep 2020 02:26:47
	System	08 Sep 2020 02:26:47

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 13:30:31

US3402211

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:30:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 13:30:31

US3402211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 12:48:26

US3402211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '8 Sep 2020'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 12:48:26

US3402211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4)	09 Sep 2020 12:48:26

US3402211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 12:48:26
	(b) (4)	

US3402211

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 12:48:30

US3402211

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'I'	System	09 Sep 2020 12:48:30

US3402211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	15 Sep 2020 18:26:15

US3402211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '15 Sep 2020'	Traci Hull (b) (4)	15 Sep 2020 18:26:15

US3402211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	15 Sep 2020 18:26:15

US3402211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	15 Sep 2020 18:26:15
	(b) (4)	

US3402211

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4)	15 Sep 2020 18:26:05
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'I'	System	15 Sep 2020 18:26:05

US3402211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	22 Sep 2020 18:37:49

US3402211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '22 Sep 2020'	(b) (4) Tammy Kohn (b) (4)	22 Sep 2020 18:37:49

US3402211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4)	22 Sep 2020 18:37:49

US3402211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	Tammy Kohn (b) (4)	22 Sep 2020 18:37:49

US3402211

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	22 Sep 2020 18:37:53

US3402211

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'I'	System	22 Sep 2020 18:37:53

US3402211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	06 Oct 2020 13:12:02
	(b) (4)	

US3402211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '6 Oct 2020'	(b) (4) Traci Hull (b) (4)	06 Oct 2020 13:12:02

US3402211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	06 Oct 2020 13:12:02

US3402211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'VISIT3'	System	06 Oct 2020 13:12:02

US3402211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	06 Oct 2020 13:12:56
	(b) (4)	

US3402211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '6 Oct 2020'	(b) (4) Traci Hull (b) (4)	06 Oct 2020 13:12:56

US3402211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '08:54'	(b) (4)	
	Traci Hull (b) (4)	06 Oct 2020 13:12:56
	(b) (4)	

US3402211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered '6 Oct 2020 08:54'	System	06 Oct 2020 13:12:56

US3402211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '98.5' F	(b) (4)	
	Traci Hull (b) (4)	06 Oct 2020 13:12:56
	(b) (4)	

US3402211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	06 Oct 2020 13:12:56

US3402211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	06 Oct 2020 13:12:56
	(b) (4)	

US3402211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '55'	Traci Hull (b) (4)	06 Oct 2020 13:12:56

US3402211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'bpm'	System	06 Oct 2020 13:12:56

US3402211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '14'	(b) (4)	
	Traci Hull (b) (4)	06 Oct 2020 13:12:56
	(b) (4)	

US3402211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'breaths/min'	System	06 Oct 2020 13:12:56

US3402211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '123'	(b) (4)	
	Traci Hull (b) (4)	06 Oct 2020 13:12:56
	(b) (4)	

US3402211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'mmHg'	System	06 Oct 2020 13:12:56

US3402211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '78'	Traci Hull (b) (4)	06 Oct 2020 13:12:56

US3402211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'mmHg'	System	06 Oct 2020 13:12:56

US3402211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05

US3402211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05

US3402211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'No (N)'	(b) (4)	
	Traci Hull (b) (4)	06 Oct 2020 13:13:19
	(b) (4)	

US3402211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered empty.	(b) (4)	06 Oct 2020 13:13:19
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	06 Oct 2020 13:13:32

US3402211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '6 Oct 2020'	(b) (4) Traci Hull (b) (4)	06 Oct 2020 13:13:32

US3402211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered '08:57'	(b) (4)	
	Traci Hull (b) (4)	06 Oct 2020 13:13:32
	(b) (4)	

US3402211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered '6 Oct 2020 08:57'	System	06 Oct 2020 13:13:32

US3402211

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:02
User entered 'Yes (Y)'	(b) (4)	06 Oct 2020 13:13:37
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered '1'	System	06 Oct 2020 13:13:37

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 64'	System	04 Aug 2020 14:29:46

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-10-06T21:58:57', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3bd1ab6e-c414-406b-8d59-634f299c81c5' User entered 'No (N)'	System	07 Oct 2020 01:59:09
	System	07 Oct 2020 01:59:09

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-10-06T21:59:01', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3bd1ab6e-c414-406b-8d59-634f299c81c5' User entered 'No (N)'	System	07 Oct 2020 01:59:09
	System	07 Oct 2020 01:59:09

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-10-06T21:59:07', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3bd1ab6e-c414-406b-8d59-634f299c81c5' User entered '06 Oct 2020 21:59:07'	System	07 Oct 2020 01:59:09
	System	07 Oct 2020 01:59:09

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 14:29:46

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 71'	System	04 Aug 2020 14:29:46

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-10-11T21:55:34', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'd40877d3-4a9a-4013-bd32-3df66de758ad' User entered 'No (N)'	System	12 Oct 2020 01:55:47
	System	12 Oct 2020 01:55:47

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-10-11T21:55:37', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'd40877d3-4a9a-4013-bd32-3df66de758ad' User entered 'No (N)'	System	12 Oct 2020 01:55:47
	System	12 Oct 2020 01:55:47

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-10-11T21:55:46', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'd40877d3-4a9a-4013-bd32-3df66de758ad' User entered '11 Oct 2020 21:55:46'	System	12 Oct 2020 01:55:47
	System	12 Oct 2020 01:55:47

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 14:29:46

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 78'	System	04 Aug 2020 14:29:46

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-10-18T22:18:24', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'cacbd89f-6f97-4ec0-be98-8ef34dbe6d0f' User entered 'No (N)'	System	19 Oct 2020 02:18:37

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-10-18T22:18:28', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'cacbd89f-6f97-4ec0-be98-8ef34dbe6d0f' User entered 'No (N)'	System	19 Oct 2020 02:18:37
	System	19 Oct 2020 02:18:37

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-10-18T22:18:33', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'cacbd89f-6f97-4ec0-be98-8ef34dbe6d0f' User entered '18 Oct 2020 22:18:33'	System	19 Oct 2020 02:18:37
	System	19 Oct 2020 02:18:37

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 14:29:46

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 92'	System	04 Aug 2020 14:29:46

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-11-01T23:18:01', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '75052c98-24b6-465d-8ea9-8a2af6b57042'	System	02 Nov 2020 04:18:16
User entered 'No (N)'	System	02 Nov 2020 04:18:16

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-11-01T23:18:07', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '75052c98-24b6-465d-8ea9-8a2af6b57042'	System	02 Nov 2020 04:18:16
User entered 'No (N)'	System	02 Nov 2020 04:18:16

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-11-01T23:18:15', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '75052c98-24b6-465d-8ea9-8a2af6b57042' User entered '01 Nov 2020 23:18:15'	System	02 Nov 2020 04:18:16
	System	02 Nov 2020 04:18:16

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 14:29:46

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 99'	System	04 Aug 2020 14:29:46

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-11-09T08:13:48', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f3191bbd-34ea-4d3f-8096-6f2030a105d5' User entered 'Yes (Y)'	System	09 Nov 2020 13:14:25
	System	09 Nov 2020 13:14:25

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-11-09T08:13:52', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f3191bbd-34ea-4d3f-8096-6f2030a105d5'	System	09 Nov 2020 13:14:25
User entered 'No (N)'	System	09 Nov 2020 13:14:25

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-11-09T08:13:57', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f3191bbd-34ea-4d3f-8096-6f2030a105d5' User entered 'No (N)'	System	09 Nov 2020 13:14:25
	System	09 Nov 2020 13:14:25

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-11-09T08:14:02', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f3191bbd-34ea-4d3f-8096-6f2030a105d5' User entered 'Yes (Y)'	System	09 Nov 2020 13:14:25
	System	09 Nov 2020 13:14:25

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-11-09T08:14:06', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f3191bbd-34ea-4d3f-8096-6f2030a105d5'	System	09 Nov 2020 13:14:25
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Nov 2020 13:14:25

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-11-09T08:14:16', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f3191bbd-34ea-4d3f-8096-6f2030a105d5' User entered '09 Nov 2020 08:14:16'	System	09 Nov 2020 13:14:25
	System	09 Nov 2020 13:14:25

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 14:29:46

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered 'Day 106'	System	04 Aug 2020 14:29:46

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-11-16T11:34:35', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '2d4ceb19-0f88-4f2b-9942-72a9e453f2f1' User entered 'No (N)'	System	16 Nov 2020 16:38:51
	System	16 Nov 2020 16:38:51

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-11-16T11:34:39', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '2d4ceb19-0f88-4f2b-9942-72a9e453f2f1'	System	16 Nov 2020 16:38:51
User entered 'No (N)'	System	16 Nov 2020 16:38:51

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-11-16T11:38:48', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '2d4ceb19-0f88-4f2b-9942-72a9e453f2f1' User entered '16 Nov 2020 11:38:48'	System	16 Nov 2020 16:38:51
	System	16 Nov 2020 16:38:51

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 14:29:46

US3402211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:42
Data entry locked.	System	04 Aug 2020 14:29:46
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 14:29:46

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-11-23T08:05:03', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3a3d00ad-7e9d-4b10-83ae-87daa2d95c8e' User entered 'No (N)'	System	23 Nov 2020 13:05:16
	System	23 Nov 2020 13:05:16

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-11-23T08:05:07', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3a3d00ad-7e9d-4b10-83ae-87daa2d95c8e' User entered 'No (N)'	System	23 Nov 2020 13:05:16
	System	23 Nov 2020 13:05:16

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-11-23T08:05:14', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3a3d00ad-7e9d-4b10-83ae-87daa2d95c8e' User entered '23 Nov 2020 08:05:14'	System	23 Nov 2020 13:05:16
	System	23 Nov 2020 13:05:16

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-11-27T19:57:49', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'b91d25fd-9b66-452c-812b-d45c04c63d60'	System	28 Nov 2020 00:57:59
User entered 'No (N)'	System	28 Nov 2020 00:57:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-11-27T19:57:52', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'b91d25fd-9b66-452c-812b-d45c04c63d60'	System	28 Nov 2020 00:57:59
User entered 'No (N)'	System	28 Nov 2020 00:57:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-11-27T19:57:57', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'b91d25fd-9b66-452c-812b-d45c04c63d60' User entered '27 Nov 2020 19:57:57'	System	28 Nov 2020 00:57:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-12-05T12:00:20', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '86428ce5-61e1-466e-b536-72760acbeebe' User entered 'No (N)'	System	05 Dec 2020 17:00:32
	System	05 Dec 2020 17:00:32

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-12-05T12:00:23', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '86428ce5-61e1-466e-b536-72760acbeebe' User entered 'No (N)'	System	05 Dec 2020 17:00:32
	System	05 Dec 2020 17:00:32

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-12-05T12:00:27', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '86428ce5-61e1-466e-b536-72760acbeebe' User entered '05 Dec 2020 12:00:27'	System	05 Dec 2020 17:00:32
	System	05 Dec 2020 17:00:32

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-12-12T16:00:26', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'a8b627bb-c0aa-40c4-85b0-647524b29ffb' User entered 'No (N)'	System	12 Dec 2020 21:00:38
	System	12 Dec 2020 21:00:38

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-12-12T16:00:29', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'a8b627bb-c0aa-40c4-85b0-647524b29ffb' User entered 'No (N)'	System	12 Dec 2020 21:00:38

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-12-12T16:00:33', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'a8b627bb-c0aa-40c4-85b0-647524b29ffb' User entered '12 Dec 2020 16:00:33'	System	12 Dec 2020 21:00:38
	System	12 Dec 2020 21:00:38

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-12-19T15:33:46', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f6b4b7d4-7aad-4de7-a7e2-77f1f28f8a40'	System	19 Dec 2020 20:33:57
User entered 'No (N)'	System	19 Dec 2020 20:33:57

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-12-19T15:33:49', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f6b4b7d4-7aad-4de7-a7e2-77f1f28f8a40'	System	19 Dec 2020 20:33:57
User entered 'No (N)'	System	19 Dec 2020 20:33:57

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-12-19T15:33:55', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'f6b4b7d4-7aad-4de7-a7e2-77f1f28f8a40' User entered '19 Dec 2020 15:33:55'	System	19 Dec 2020 20:33:57
	System	19 Dec 2020 20:33:57

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-12-24T21:32:26', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '4cd3ef3a-b6af-4304-a175-c6a9ec385d21'	System	25 Dec 2020 02:32:36
User entered 'No (N)'	System	25 Dec 2020 02:32:36

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-12-24T21:32:29', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '4cd3ef3a-b6af-4304-a175-c6a9ec385d21'	System	25 Dec 2020 02:32:36
User entered 'No (N)'	System	25 Dec 2020 02:32:36

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2020-12-24T21:32:32', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '4cd3ef3a-b6af-4304-a175-c6a9ec385d21' User entered '24 Dec 2020 21:32:32'	System	25 Dec 2020 02:32:36

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-01-02T12:24:44', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ede183af-cea8-4e69-a5c9-faadb3b227f' User entered 'No (N)'	System	02 Jan 2021 17:25:02

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-01-02T12:24:49', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ede183af-cea8-4e69-a5c9-faadb3b227f' User entered 'No (N)'	System	02 Jan 2021 17:25:02

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-01-02T12:24:59', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ede183af-cea8-4e69-a5c9-faadfb3b227f' User entered '02 Jan 2021 12:24:59'	System	02 Jan 2021 17:25:02

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-01-08T22:01:43', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'bafb4453-b3b9-4c04-a672-29a850077d60'	System	09 Jan 2021 03:01:56
User entered 'No (N)'	System	09 Jan 2021 03:01:56

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-01-08T22:01:46', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'bafb4453-b3b9-4c04-a672-29a850077d60'	System	09 Jan 2021 03:01:56
User entered 'No (N)'	System	09 Jan 2021 03:01:56

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-01-08T22:01:52', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'bafb4453-b3b9-4c04-a672-29a850077d60' User entered '08 Jan 2021 22:01:52'	System	09 Jan 2021 03:01:56
	System	09 Jan 2021 03:01:56

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-01-14T21:24:34', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'b53d9df2-61b3-4ec4-ab59-fdf55579ea47'	System	15 Jan 2021 02:24:49
User entered 'No (N)'	System	15 Jan 2021 02:24:49

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-01-14T21:24:38', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'b53d9df2-61b3-4ec4-ab59-fdf55579ea47'	System	15 Jan 2021 02:24:49
User entered 'No (N)'	System	15 Jan 2021 02:24:49

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-01-14T21:24:43', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'b53d9df2-61b3-4ec4-ab59-fdf55579ea47' User entered '14 Jan 2021 21:24:43'	System	15 Jan 2021 02:24:49

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-01-22T22:52:24', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '824c97db-c650-4145-9055-5581f3f7dcf7'	System	23 Jan 2021 03:52:34
User entered 'No (N)'	System	23 Jan 2021 03:52:34

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-01-22T22:52:27', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '824c97db-c650-4145-9055-5581f3f7dcf7'	System	23 Jan 2021 03:52:34
User entered 'No (N)'	System	23 Jan 2021 03:52:34

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-01-22T22:52:30', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '824c97db-c650-4145-9055-5581f3f7dcf7'	System	23 Jan 2021 03:52:34
User entered '22 Jan 2021 22:52:30'	System	23 Jan 2021 03:52:34

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-01-30T10:49:18', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'c02edd05-fc89-4624-a446-eafe0de93aa9' User entered 'No (N)'	System	30 Jan 2021 15:49:31
	System	30 Jan 2021 15:49:31

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-01-30T10:49:22', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'c02edd05-fc89-4624-a446-eafe0de93aa9'	System	30 Jan 2021 15:49:31
User entered 'No (N)'	System	30 Jan 2021 15:49:31

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-01-30T10:49:28', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'c02edd05-fc89-4624-a446-eafe0de93aa9' User entered '30 Jan 2021 10:49:28'	System	30 Jan 2021 15:49:31

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-02-05T12:22:35', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3994b5dc-90f6-46d1-914e-5f9367bd6254' User entered 'No (N)'	System	05 Feb 2021 17:22:44
	System	05 Feb 2021 17:22:44

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-02-05T12:22:38', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3994b5dc-90f6-46d1-914e-5f9367bd6254' User entered 'No (N)'	System	05 Feb 2021 17:22:44
	System	05 Feb 2021 17:22:44

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-02-05T12:22:41', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '3994b5dc-90f6-46d1-914e-5f9367bd6254' User entered '05 Feb 2021 12:22:41'	System	05 Feb 2021 17:22:44
	System	05 Feb 2021 17:22:44

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-02-11T11:14:38', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'b3c64983-2267-4f10-963a-d0d4ea53b7d1' User entered 'No (N)'	System	11 Feb 2021 16:14:49

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-02-11T11:14:40', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'b3c64983-2267-4f10-963a-d0d4ea53b7d1' User entered 'No (N)'	System	11 Feb 2021 16:14:49

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-02-11T11:14:43', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'b3c64983-2267-4f10-963a-d0d4ea53b7d1' User entered '11 Feb 2021 11:14:43'	System	11 Feb 2021 16:14:49
	System	11 Feb 2021 16:14:49

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-02-20T12:00:12', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '77204ac0-5c23-45e3-87d9-44589e19e931' User entered 'No (N)'	System	20 Feb 2021 17:00:59
	System	20 Feb 2021 17:00:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-02-20T12:00:15', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '77204ac0-5c23-45e3-87d9-44589e19e931' User entered 'No (N)'	System	20 Feb 2021 17:00:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-02-20T12:00:19', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '77204ac0-5c23-45e3-87d9-44589e19e931' User entered '20 Feb 2021 12:00:19'	System	20 Feb 2021 17:00:59
	System	20 Feb 2021 17:00:59

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-02-27T12:08:10-05:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '5429fd91-594b-49f7-a5d4-57e4d7ef76f0'	System	27 Feb 2021 17:13:24
User entered 'No (N)'	System	27 Feb 2021 17:13:24

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-02-27T12:08:13-05:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '5429fd91-594b-49f7-a5d4-57e4d7ef76f0'	System	27 Feb 2021 17:13:24
User entered 'No (N)'	System	27 Feb 2021 17:13:24

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-02-27T12:08:17-05:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '5429fd91-594b-49f7-a5d4-57e4d7ef76f0'	System	27 Feb 2021 17:13:24
User entered '27 Feb 2021 17:08:17'	System	27 Feb 2021 17:13:24

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-03-05T18:24:12-05:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '00ae4551-6e85-434d-a54d-e9e0fcc456d4'	System	05 Mar 2021 23:24:25
User entered 'No (N)'	System	05 Mar 2021 23:24:25

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-03-05T18:24:18-05:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '00ae4551-6e85-434d-a54d-e9e0fcc456d4'	System	05 Mar 2021 23:24:25
User entered 'No (N)'	System	05 Mar 2021 23:24:25

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-03-05T18:24:22-05:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '00ae4551-6e85-434d-a54d-e9e0fcc456d4' User entered '05 Mar 2021 18:24:22'	System	05 Mar 2021 23:24:25
	System	05 Mar 2021 23:24:25

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-03-12T10:07:25-05:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ebb1cbf1-b915-4b2c-a5e1-314a0166418b' User entered 'Yes (Y)'	System	12 Mar 2021 15:08:11
	System	12 Mar 2021 15:08:11

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-03-12T10:07:28-05:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ebb1cbf1-b915-4b2c-a5e1-314a0166418b'	System	12 Mar 2021 15:08:11
User entered 'No (N)'	System	12 Mar 2021 15:08:11

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-03-12T10:07:30-05:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ebb1cbf1-b915-4b2c-a5e1-314a0166418b'	System	12 Mar 2021 15:08:11
User entered 'No (N)'	System	12 Mar 2021 15:08:11

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-03-12T10:07:38-05:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ebb1cbf1-b915-4b2c-a5e1-314a0166418b' User entered 'Yes (Y)'	System	12 Mar 2021 15:08:11
	System	12 Mar 2021 15:08:11

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-03-12T10:07:43-05:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ebb1cbf1-b915-4b2c-a5e1-314a0166418b'	System	12 Mar 2021 15:08:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Mar 2021 15:08:11

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-03-12T10:07:59-05:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'ebb1cbf1-b915-4b2c-a5e1-314a0166418b' User entered '12 Mar 2021 10:07:59'	System	12 Mar 2021 15:08:11
	System	12 Mar 2021 15:08:11

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-03-19T10:31:17-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e0b49ad3-93c6-4574-b075-06af0078f368'	System	19 Mar 2021 14:31:50
User entered 'Yes (Y)'	System	19 Mar 2021 14:31:50

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-03-19T10:31:19-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e0b49ad3-93c6-4574-b075-06af0078f368'	System	19 Mar 2021 14:31:50
User entered 'No (N)'	System	19 Mar 2021 14:31:50

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-03-19T10:31:22-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e0b49ad3-93c6-4574-b075-06af0078f368'	System	19 Mar 2021 14:31:50
User entered 'No (N)'	System	19 Mar 2021 14:31:50

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-03-19T10:31:33-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e0b49ad3-93c6-4574-b075-06af0078f368'	System	19 Mar 2021 14:31:50
User entered 'Yes (Y)'	System	19 Mar 2021 14:31:50

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-03-19T10:31:36-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e0b49ad3-93c6-4574-b075-06af0078f368'	System	19 Mar 2021 14:31:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Mar 2021 14:31:50

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-03-19T10:31:39-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e0b49ad3-93c6-4574-b075-06af0078f368'	System	19 Mar 2021 14:31:50
User entered '19 Mar 2021 10:31:39'	System	19 Mar 2021 14:31:50

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-04-02T10:29:05-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'b36b2754-0363-4564-a384-dab0533606e3'	System	02 Apr 2021 14:29:16
User entered 'No (N)'	System	02 Apr 2021 14:29:16

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-04-02T10:29:08-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'b36b2754-0363-4564-a384-dab0533606e3'	System	02 Apr 2021 14:29:16
User entered 'No (N)'	System	02 Apr 2021 14:29:16

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-04-02T10:29:11-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'b36b2754-0363-4564-a384-dab0533606e3'	System	02 Apr 2021 14:29:16
User entered '02 Apr 2021 10:29:11'	System	02 Apr 2021 14:29:16

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-04-09T14:01:29-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '1d3ffc71-7d97-4929-b2e3-68611f24ed69'	System	09 Apr 2021 18:01:39
User entered 'No (N)'	System	09 Apr 2021 18:01:39

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-04-09T14:01:32-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '1d3ffc71-7d97-4929-b2e3-68611f24ed69'	System	09 Apr 2021 18:01:39
User entered 'No (N)'	System	09 Apr 2021 18:01:39

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-04-09T14:01:37-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '1d3ffc71-7d97-4929-b2e3-68611f24ed69'	System	09 Apr 2021 18:01:39
User entered '09 Apr 2021 14:01:37'	System	09 Apr 2021 18:01:39

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-04-17T12:01:41-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '07ccf86d-29ad-48b7-a119-9944262f276e' User entered 'Yes (Y)'	System	17 Apr 2021 16:05:37
	System	17 Apr 2021 16:05:37

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-04-17T12:01:43-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '07ccf86d-29ad-48b7-a119-9944262f276e'	System	17 Apr 2021 16:05:37
User entered 'No (N)'	System	17 Apr 2021 16:05:37

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-04-17T12:01:46-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '07ccf86d-29ad-48b7-a119-9944262f276e'	System	17 Apr 2021 16:05:37
User entered 'No (N)'	System	17 Apr 2021 16:05:37

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-04-17T12:01:50-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '07ccf86d-29ad-48b7-a119-9944262f276e' User entered 'Yes (Y)'	System	17 Apr 2021 16:05:37
	System	17 Apr 2021 16:05:37

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-04-17T12:01:53-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '07ccf86d-29ad-48b7-a119-9944262f276e'	System	17 Apr 2021 16:05:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Apr 2021 16:05:37

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-04-17T12:01:56-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '07ccf86d-29ad-48b7-a119-9944262f276e'	System	17 Apr 2021 16:05:37
User entered '17 Apr 2021 12:01:56'	System	17 Apr 2021 16:05:37

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-04-23T14:03:55-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e423627d-2996-48bd-972a-5fed11a3cfca' User entered 'No (N)'	System	23 Apr 2021 18:04:05
	System	23 Apr 2021 18:04:05

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-04-23T14:03:58-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e423627d-2996-48bd-972a-5fed11a3cfca' User entered 'No (N)'	System	23 Apr 2021 18:04:05

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-04-23T14:04:02-04:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: 'e423627d-2996-48bd-972a-5fed11a3cfca'	System	23 Apr 2021 18:04:05
User entered '23 Apr 2021 14:04:02'	System	23 Apr 2021 18:04:05

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:19:08

US3402211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:30:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:08
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:19:08

US3402211

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:30:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:28:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-02-27T12:08:21-05:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '382dbdfb-1403-4403-83ff-497f33118b43'	System	27 Feb 2021 17:13:32
User entered 'No (N)'	System	27 Feb 2021 17:13:32

US3402211

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:30:30

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:28:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9A328E38-8E17-4531-87DE-E2EAB41CE81E)', Time: '2021-02-27T12:08:25-05:00', User OID: 'PatientReportedOutcome (US3402211)', ODM File OID: '382dbdfb-1403-4403-83ff-497f33118b43' User entered '27 Feb 2021 17:08:25'	System	27 Feb 2021 17:13:32
	System	27 Feb 2021 17:13:32

US3402211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:20:35
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	26 Oct 2020 18:00:27
	(b) (4)	

US3402211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:20:35
User entered '26 Oct 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	26 Oct 2020 18:00:27

US3402211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:20:35
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	26 Oct 2020 18:00:27

US3402211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:20:35
User entered empty.	(b) (4) Traci Hull (b) (4)	26 Oct 2020 18:00:27

US3402211

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:20:35
User entered 'Yes (Y)'	Traci Hull (b) (4)	26 Oct 2020 18:00:38

US3402211

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:05
User entered 'I'	System	26 Oct 2020 18:00:38

US3402211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4)	30 Nov 2020 21:09:00
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '30 Nov 2020'	Traci Hull (b) (4)	30 Nov 2020 21:09:00

US3402211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	30 Nov 2020 21:09:00

US3402211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	30 Nov 2020 21:09:00
	(b) (4)	

US3402211

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4)	30 Nov 2020 21:08:52
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:31
User entered '1'	System	30 Nov 2020 21:08:52

US3402211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	29 Dec 2020 18:20:03

US3402211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '29 Dec 2020'	Traci Hull (b) (4)	29 Dec 2020 18:20:03

US3402211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	29 Dec 2020 18:20:03

US3402211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	29 Dec 2020 18:20:03
	(b) (4)	

US3402211

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	29 Dec 2020 18:20:10

US3402211

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:31
User entered 'I'	System	29 Dec 2020 18:20:10

US3402211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	08 Feb 2021 16:26:30

US3402211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '29 Jan 2021'	Tammy Kohn (b) (4)	08 Feb 2021 16:26:30

US3402211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tammy Kohn (b) (4)	08 Feb 2021 16:26:30

US3402211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered empty.	(b) (4) Tammy Kohn (b) (4)	08 Feb 2021 16:26:30

US3402211

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	08 Feb 2021 16:26:33

US3402211

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:31
User entered '1'	System	08 Feb 2021 16:26:33

US3402211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Mar 2021 16:02:15

US3402211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '3 Mar 2021'	(b) (4)	
	Traci Hull (b) (4)	03 Mar 2021 16:02:15
	(b) (4)	

US3402211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Mar 2021 16:02:15

US3402211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User entered 'VISIT4'	System	03 Mar 2021 16:02:15

US3402211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 13:24:37

US3402211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '3 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 13:24:37

US3402211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '08:50'	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 13:24:37

US3402211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User entered '3 Mar 2021 08:50'	System	31 Mar 2021 13:24:37

US3402211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '36.6' C	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 13:24:37

US3402211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Oral (Oral)'	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 13:24:37
	(b) (4)	

US3402211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 13:24:37

US3402211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '54'	Tammy Kohn (b) (4)	31 Mar 2021 13:24:37

US3402211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User entered 'bpm'	System	31 Mar 2021 13:24:37

US3402211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '18'	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 13:24:37

US3402211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User entered 'breaths/min'	System	31 Mar 2021 13:24:37

US3402211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '118'	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 13:24:37

US3402211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User entered 'mmHg'	System	31 Mar 2021 13:24:37

US3402211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '60'	Tammy Kohn (b) (4)	31 Mar 2021 13:24:37

US3402211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User entered 'mmHg'	System	31 Mar 2021 13:24:37

US3402211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02

US3402211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02

US3402211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'No (N)'	(b) (4)	
	Traci Hull (b) (4)	03 Mar 2021 16:02:19
	(b) (4)	

US3402211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered empty.	(b) (4)	03 Mar 2021 16:02:19
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Mar 2021 16:02:34

US3402211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '3 Mar 2021'	(b) (4) Traci Hull (b) (4)	03 Mar 2021 16:02:34

US3402211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '08:56'	(b) (4) Traci Hull (b) (4)	03 Mar 2021 16:02:34

US3402211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User entered '3 Mar 2021 08:56'	System	03 Mar 2021 16:02:34

US3402211

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Mar 2021 16:02:38

US3402211

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:42:02
User entered 'I'	System	03 Mar 2021 16:02:38

US3402211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	30 Mar 2021 19:30:20
	(b) (4)	

US3402211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
	(b) (4)	
User entered '30 Mar 2021'	Traci Hull (b) (4)	30 Mar 2021 19:30:20
	(b) (4)	

US3402211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4) (b) (4)	30 Mar 2021 19:30:20

US3402211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	30 Mar 2021 19:30:20
	(b) (4)	

US3402211

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	30 Mar 2021 19:30:27
	(b) (4)	

US3402211

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 19:30:27

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4)	08 Jan 2021 16:28:51
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '08 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	08 Jan 2021 16:28:51
	(b) (4)	

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	08 Jan 2021 16:28:51

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 16:28:51

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:30:30

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '06 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	08 Jan 2021 16:30:11
	(b) (4)	

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:30:30

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '0'	(b) (4) Tammy Kohn (b) (4)	09 Apr 2021 13:17:17
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 11:20:00

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:30:30

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4)	08 Jan 2021 16:30:11
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:30:30

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Apr 2021 05:58:11
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 13:17:20
User entered 'Amendment 6 or later (Amendment 6 or later)'	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 13:17:17
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 15:41:38
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:20:00

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:30:30

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '08 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	08 Jan 2021 16:30:11
	(b) (4)	

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:30:30

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Placebo (Placebo)'	Traci Hull (b) (4)	08 Jan 2021 16:30:11

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:30:30

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 06:08:31
User entered 'Placebo (Placebo)'	Traci Hull (b) (4)	08 Jan 2021 16:30:11
	(b) (4)	

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:30:30

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 06:08:31
User entered 'Placebo (Placebo)'	Traci Hull (b) (4)	08 Jan 2021 16:30:11
	(b) (4)	

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:30:30

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4)	08 Jan 2021 16:30:11
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:30:30

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered '1'	System	08 Jan 2021 16:30:11

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:30:30

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'I'	System	08 Jan 2021 16:30:11

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered empty.	System	08 Jan 2021 16:32:46
DataPoint set to visible.	System	08 Jan 2021 16:30:11

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered empty.	System	08 Jan 2021 16:32:46
DataPoint set to visible.	System	08 Jan 2021 16:30:11

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '08 Jan 2021'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '09:23'	Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered '08 Jan 2021 09:23'	System	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '37.2' C	(b) (4)	
	Traci Hull (b) (4)	08 Jan 2021 16:32:46
	(b) (4)	

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered empty.	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '68'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'bpm'	System	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '18'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'breaths/min'	System	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '116'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'mmHg'	System	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '68'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'mmHg'	System	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:30:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered empty.	System	08 Jan 2021 16:32:46
DataPoint set to visible.	System	08 Jan 2021 16:30:11

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '08 Jan 2021'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '10:46'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered '08 Jan 2021 10:46'	System	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '37.2' C	(b) (4)	
	Traci Hull (b) (4)	08 Jan 2021 16:32:46
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered empty.	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '76'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'bpm'	System	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '18'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'breaths/min'	System	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '116'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'mmHg'	System	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '68'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'mmHg'	System	08 Jan 2021 16:32:46

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4)	08 Jan 2021 16:33:11
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '08 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	08 Jan 2021 16:33:11
	(b) (4)	

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:33:45

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered empty.	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:33:45

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered empty.	Traci Hull (b) (4)	08 Jan 2021 16:33:45

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'mRNA-1273'	System	08 Jan 2021 16:33:45
DataPoint set to visible.	System	08 Jan 2021 16:30:11

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '08 Jan 2021'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:33:45

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '09:45'	Traci Hull (b) (4)	08 Jan 2021 16:33:45

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered '08 Jan 2021 09:45'	System	08 Jan 2021 16:33:45

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Left Arm (LEFT ARM)'	Traci Hull (b) (4)	08 Jan 2021 16:33:45

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'ONCE'	System	08 Jan 2021 16:33:45

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'INTRAMUSCULAR'	System	08 Jan 2021 16:33:45

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:30:29

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '08 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	08 Jan 2021 16:30:29
	(b) (4)	

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '09:16'	(b) (4)	
	Traci Hull (b) (4)	08 Jan 2021 16:30:29
	(b) (4)	

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered '08 Jan 2021 09:16'	System	08 Jan 2021 16:30:29

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:30:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:30:47

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:30:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '08 Jan 2021'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:30:47

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:30:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '09:09'	(b) (4)	
	Traci Hull (b) (4)	08 Jan 2021 16:30:47
	(b) (4)	

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:30:30

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered '08 Jan 2021 09:09'	System	08 Jan 2021 16:30:47

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	08 Jan 2021 16:30:53

US3402211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered '1'	System	08 Jan 2021 16:30:53

US3402211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	18 Jan 2021 14:55:45

US3402211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '15 Jan 2021'	(b) (4) Tammy Kohn (b) (4)	18 Jan 2021 14:55:45

US3402211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4)	18 Jan 2021 14:55:45

US3402211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered empty.	Tammy Kohn (b) (4)	18 Jan 2021 14:55:45

US3402211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	18 Jan 2021 14:55:49

US3402211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'I'	System	18 Jan 2021 14:55:49

US3402211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered '1'	System	18 Jan 2021 14:55:49
DataPoint set to visible.	System	18 Jan 2021 14:55:49

US3402211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4)	05 Feb 2021 20:56:53
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '5 Feb 2021'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 20:56:53

US3402211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	05 Feb 2021 20:56:53

US3402211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'OLD29'	System	05 Feb 2021 20:56:53

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '5 Feb 2021'	(b) (4) Traci Hull (b) (4) (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '12:17'	(b) (4)	05 Feb 2021 20:58:26
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered '5 Feb 2021 12:17'	System	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '36.9' C	Traci Hull (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered empty.	(b) (4) Traci Hull (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '53'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'bpm'	System	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '17'	Traci Hull (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'breaths/min'	System	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '156'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'mmHg'	System	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '89'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:30:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'mmHg'	System	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '5 Feb 2021'	(b) (4) Traci Hull (b) (4) (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '13:25'	(b) (4)	05 Feb 2021 20:58:26
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered '5 Feb 2021 13:25'	System	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '36.8' C	Traci Hull (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered empty.	(b) (4)	05 Feb 2021 20:58:26
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '56'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'bpm'	System	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '16'	Traci Hull (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'breaths/min'	System	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '143'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'mmHg'	System	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '85'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:30:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'mmHg'	System	05 Feb 2021 20:58:26

US3402211

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4)	05 Feb 2021 20:58:35
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '5 Feb 2021'	(b) (4)	
	Traci Hull (b) (4)	05 Feb 2021 20:58:35
	(b) (4)	

US3402211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4)	05 Feb 2021 21:00:32
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered empty.	(b) (4) Traci Hull (b) (4)	05 Feb 2021 21:00:32

US3402211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered empty.	Traci Hull (b) (4)	05 Feb 2021 21:00:32

US3402211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'mRNA-1273'	System	05 Feb 2021 21:00:32
DataPoint set to visible.	System	18 Jan 2021 14:55:49

US3402211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '5 Feb 2021'	(b) (4)	
	Traci Hull (b) (4)	05 Feb 2021 21:00:32
	(b) (4)	

US3402211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '12:50'	(b) (4)	05 Feb 2021 21:00:32
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered '5 Feb 2021 12:50'	System	05 Feb 2021 21:00:32

US3402211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Left Arm (LEFT ARM)'	Traci Hull (b) (4)	05 Feb 2021 21:00:32

US3402211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'ONCE'	System	05 Feb 2021 21:00:32

US3402211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:30:30

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'INTRAMUSCULAR'	System	05 Feb 2021 21:00:32

US3402211

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 21:00:37

US3402211

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'I'	System	05 Feb 2021 21:00:37

US3402211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4)	15 Feb 2021 12:38:05
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '12 Feb 2021'	(b) (4) Traci Hull (b) (4) (b) (4)	15 Feb 2021 12:38:05

US3402211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	15 Feb 2021 12:38:05

US3402211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:30:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered empty.	Traci Hull (b) (4)	15 Feb 2021 12:38:05

US3402211

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4)	15 Feb 2021 12:38:11
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:30:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'I'	System	15 Feb 2021 12:38:11

US3402211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4)	03 Mar 2021 16:03:22
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '3 Mar 2021'	(b) (4) Traci Hull (b) (4)	03 Mar 2021 16:03:22

US3402211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Mar 2021 16:03:22

US3402211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:30:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'OLD57'	System	03 Mar 2021 16:03:22

US3402211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User closed query 'Per CDM: Visit 4 Day 209 and Visit OL-D57 are both dated 03Mar2021, however, Vital Signs 'Was the Vital Signs assessed?' is YES and data is present at this visit. But at Visit 4 Day 209 'Was the Vital Signs assessed?' is blank. If the visits occurred on the same day, then the sample collection data should be entered at both visits per sponsor. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 07:52:08
Query 'Per CDM: Visit 4 Day 209 and Visit OL-D57 are both dated 03Mar2021, however, Vital Signs 'Was the Vital Signs assessed?' is YES and data is present at this visit. But at Visit 4 Day 209 'Was the Vital Signs assessed?' is blank. If the visits occurred on the same day, then the sample collection data should be entered at both visits per sponsor. Please review and update as appropriate. ' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 13:24:07
User opened query 'Per CDM: Visit 4 Day 209 and Visit OL-D57 are both dated 03Mar2021, however, Vital Signs 'Was the Vital Signs assessed?' is YES and data is present at this visit. But at Visit 4 Day 209 'Was the Vital Signs assessed?' is blank. If the visits occurred on the same day, then the sample collection data should be entered at both visits per sponsor. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 03:23:57
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Mar 2021 16:03:53

US3402211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '3 Mar 2021'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Mar 2021 16:03:53

US3402211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '08:50'	(b) (4)	
	Traci Hull (b) (4)	03 Mar 2021 16:03:53
	(b) (4)	

US3402211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered '3 Mar 2021 08:50'	System	03 Mar 2021 16:03:53

US3402211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '36.6' C	Traci Hull (b) (4)	03 Mar 2021 16:03:53

US3402211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	03 Mar 2021 16:03:53

US3402211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	03 Mar 2021 16:03:53
	(b) (4)	

US3402211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '54'	Traci Hull (b) (4)	03 Mar 2021 16:03:53

US3402211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'bpm'	System	03 Mar 2021 16:03:53

US3402211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '18'	Traci Hull (b) (4)	03 Mar 2021 16:03:53

US3402211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'breaths/min'	System	03 Mar 2021 16:03:53

US3402211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '118'	(b) (4) Traci Hull (b) (4)	03 Mar 2021 16:03:53

US3402211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'mmHg'	System	03 Mar 2021 16:03:53

US3402211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '60'	(b) (4) Traci Hull (b) (4)	03 Mar 2021 16:03:53

US3402211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered 'mmHg'	System	03 Mar 2021 16:03:53

US3402211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52

US3402211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:30:30

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52

US3402211

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'No (N)'	(b) (4)	03 Mar 2021 16:04:07
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:30:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered empty.	(b) (4)	03 Mar 2021 16:04:07
	Traci Hull (b) (4)	
	(b) (4)	

US3402211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Mar 2021 16:04:21

US3402211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '3 Mar 2021'	(b) (4) Traci Hull (b) (4)	03 Mar 2021 16:04:21

US3402211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
User entered '08:56'	(b) (4) Traci Hull (b) (4)	03 Mar 2021 16:04:21

US3402211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:30:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:24:52
User entered '3 Mar 2021 08:56'	System	03 Mar 2021 16:04:21

US3402211

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:30:30

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:40
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:38:00
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	13 Nov 2020 13:44:19
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 20:50:54

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:32:24
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 13:46:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 13:46:45
Data point term sent to Coder	System	13 Nov 2020 13:46:07
User entered 'Urinary Tract Infection'	Jennifer Molstead (b) (4) (b) (4)	13 Nov 2020 13:45:31

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:32:25
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	21 Jan 2021 17:32:27
User entered 'No (N)'	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:32:28
User entered 'No (N)'	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	21 Jan 2021 17:32:31
User entered '07 Nov 2020'	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:32:33
User entered empty.	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User entered empty.	System	13 Nov 2020 13:45:31

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:32:35
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 07:17:20
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	19 Jan 2021 20:36:44
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Jan 2021 20:36:36
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 02:42:12
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	13 Nov 2020 13:45:31

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User closed query 'There is no end date in source document. Please review and update entries.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:01:29
Query 'There is no end date in source document. Please review and update entries.' answered with 'ONCE SOURCE IS RECEIVED BACK IT WILL BE UPDATED TO THE 19 NOV 2020' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 19:28:44
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:32:36
User opened query 'There is no end date in source document. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 17:31:30
User entered '19 Nov 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Jan 2021 20:36:36
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	13 Nov 2020 13:45:31

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:32:38
User entered empty.	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User entered empty.	System	13 Nov 2020 13:45:31

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:32:40
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	21 Jan 2021 17:32:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:32:44
User entered '0'	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:32:46
User entered '0'	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:32:48
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	13 Nov 2020 13:45:31

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:32:50
User entered empty.	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	21 Jan 2021 17:32:53
User entered empty.	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:32:56
User entered empty.	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:32:58
User entered empty.	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:33:01
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	13 Nov 2020 13:45:31

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:33:03
User entered '0'	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:33:05
User entered '0'	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:33:07
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 10:29:45
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 13:45:29
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 13:45:24
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:09:28
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4) (b) (4)	13 Nov 2020 13:45:31

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:33:09
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 04:59:08
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate.' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 19:04:57
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 19:04:49
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 10:29:38
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4) (b) (4)	13 Nov 2020 13:45:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:33:11
User closed query 'Per CDM: Action taken with IP should be recorded as NOT APPLICABLE if the AE started after the second dose. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 04:59:06
Query 'Per CDM: Action taken with IP should be recorded as NOT APPLICABLE if the AE started after the second dose. Please update accordingly.' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 19:05:01
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 19:04:49
User opened query 'Per CDM: Action taken with IP should be recorded as NOT APPLICABLE if the AE started after the second dose. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 10:27:46
User entered 'None (NONE)'	Jennifer Molstead (b) (4) (b) (4)	13 Nov 2020 13:45:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:33:13
User entered '0'	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:33:15
User entered 'l'	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:33:17
User entered '0'	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:33:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Jan 2021 20:36:36
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jennifer Molstead (b) (4) (b) (4)	13 Nov 2020 13:45:31

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:33:20
User entered empty.	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	21 Jan 2021 17:33:22
User entered empty.	Jennifer Molstead (b) (4)	13 Nov 2020 13:45:31

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User entered '0'	System	13 Nov 2020 13:45:31

US3402211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33
User entered '1'	System	13 Nov 2020 13:45:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:30:30

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:00
User coded data point as SOC: Investigations, HLT: Metabolic, nutritional and blood gas investigations, HLT: Carbohydrate tolerance analyses (incl diabetes), PT: Glycosylated haemoglobin increased, LLT: Hemoglobin A1C increased - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 20:35:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 20:35:46
Data point term sent to Coder	System	16 Nov 2020 13:29:23
User entered 'INTERMITTEN ELEVATED A1C'	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:34:01
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 13:29:10

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:34:03
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 13:29:10

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:34:05
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 13:29:10

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:07
User entered '30 Oct 2020'	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:09
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	16 Nov 2020 13:29:35
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	16 Nov 2020 13:29:35
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	16 Nov 2020 13:29:10
User entered '12:00'	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 13:29:35
User entered '30 Oct 2020 12:00'	System	16 Nov 2020 13:29:10

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:11
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:12
User entered empty.	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:14
User entered empty.	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 13:29:10

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:17
User entered 'Grade 1/Mild (Grade 1/Mild)'	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:18
User entered 'No (N)'	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:20
User entered '0'	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:22
User entered '0'	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:24
User entered '0'	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:25
User entered empty.	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:34:28
User entered empty.	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 13:29:10

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:30
User entered empty.	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:34:31
User entered empty.	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 13:29:10

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:33
User entered '0'	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:35
User entered '0'	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:36
User entered '0'	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:38
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 10:31:20
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 13:45:48
User entered 'Not Related (NOT RELATED)'	Tammy Kohn (b) (4)	18 Nov 2020 13:45:43
reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:47:03
User entered 'Not Applicable (NOT APPLICABLE)'	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 13:29:10

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:41
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 16:00:05
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. ' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4)	23 Nov 2020 19:05:22
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Tammy Kohn (b) (4)	23 Nov 2020 19:05:18
reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 10:31:18
User entered 'Not Applicable (NOT APPLICABLE)'	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:42
User closed query 'Per CDM: Action taken with IP should be recorded as NOT APPLICABLE if the AE started after the second dose. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 16:01:08
Query 'Per CDM: Action taken with IP should be recorded as NOT APPLICABLE if the AE started after the second dose. Please update accordingly. ' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4)	23 Nov 2020 19:05:26
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	23 Nov 2020 19:05:18
	(b) (4)	
User opened query 'Per CDM: Action taken with IP should be recorded as NOT APPLICABLE if the AE started after the second dose. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 10:31:48
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 13:29:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 13:29:35
User entered 'None (NONE)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	16 Nov 2020 13:29:35
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 13:29:10
User entered empty.	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:46
User entered 'I'	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:47
User entered '0'	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:49
User entered '0'	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:34:50
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 13:29:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:34:52
User entered empty.	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 13:29:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:34:54
User entered empty.	Tammy Kohn (b) (4)	16 Nov 2020 13:29:10
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Nov 2020 13:29:10

US3402211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:30:30

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Nov 2020 13:29:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:36:09
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:20
User entered	System	30 Dec 2020 15:15:14
'USA-US059-2020-mRNA-1273-P301000026'		
User entered 'New'	(b) (4), (b) (6)	30 Dec 2020 15:15:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:36:11
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Intraductal proliferative breast lesion, LLT: Carcinoma in situ of breast ductal - version MedDRA\23.0.	Coder Import (b) (4)	29 Dec 2020 21:18:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Dec 2020 21:18:21
Data point term sent to Coder	System	29 Dec 2020 20:06:36
User entered 'Ductal carcinoma Insitu Right Breast'	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:36:13
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	29 Dec 2020 20:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	29 Dec 2020 20:05:59

US3402211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	29 Dec 2020 20:05:59

US3402211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered '23 Oct 2020'	Jennifer Molstead (b) (4) (b) (4)	29 Dec 2020 20:05:59

US3402211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	29 Dec 2020 20:05:59

US3402211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Dec 2020 20:05:59

US3402211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered 'No (N)'	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered '23 Dec 2020'	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	29 Dec 2020 20:05:59

US3402211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Dec 2020 20:05:59

US3402211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Molstead (b) (4) (b) (4)	29 Dec 2020 20:05:59

US3402211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered '0'	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered '0'	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered '0'	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	29 Dec 2020 20:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	29 Dec 2020 20:05:59

US3402211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	29 Dec 2020 20:05:59

US3402211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered empty.	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered '0'	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59
	(b) (4)	

US3402211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered '0'	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered 'I'	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59
	(b) (4)	

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:37:02
User closed query 'PV Query Urgent: PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety). Query 'PV Query Urgent: PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'data updated' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 17:31:08
Query 'PV Query Urgent: PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'data updated' (Site from Safety).	Tammy Kohn (b) (4)	19 Jan 2021 20:37:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	19 Jan 2021 20:37:27
	(b) (4)	
User opened query 'PV Query Urgent: PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 14:49:57
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:37:02
User closed query 'PV Query Urgent: PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety). Query 'PV Query Urgent: PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'DATA UPDATED' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 18:47:12
	Tammy Kohn (b) (4)	07 Jan 2021 17:26:08
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	07 Jan 2021 17:25:32
	(b) (4)	
User opened query 'PV Query Urgent: PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 16:40:59
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:37:02
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 18:47:15
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' answered with 'DATA UPDATED' (Site from Safety).	Tammy Kohn (b) (4)	07 Jan 2021 17:26:46
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	07 Jan 2021 17:26:31
	(b) (4)	
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 16:41:30
User entered 'None (NONE)'	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered '0'	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered '0'	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered 'I'	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Jennifer Molstead (b) (4) (b) (4)	29 Dec 2020 20:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:47:21
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Un-verified.	Jennifer Molstead (b) (4)	14 Mar 2021 16:29:44
User entered 'Subject has been given the choice of radiation or tamoxafin. she has yet to decide.' reason for change: New Information	Jennifer Molstead (b) (4)	14 Mar 2021 16:29:44
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:37:02
User entered 'Subject is waiting for Pathology report for the next course of action.'	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:47:29
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User closed query 'PV Query: Please provide lumpectomy pathology results. Please leave query unanswered until information is available or, if unable to obtain, please state so' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 14:24:43
User closed query 'PV Query: Please provide any additional relevant labs and diagnostic test results. Please leave query unanswered until information is available or, if unable to obtain, please state so. '	(b) (4), (b) (6)	15 Mar 2021 14:24:39
(Site from Safety).		
Query 'PV Query: Please provide lumpectomy pathology results. Please leave query unanswered until information is available or, if unable to obtain, please state so' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	14 Mar 2021 16:30:02
Query 'PV Query: Please provide any additional relevant labs and diagnostic test results. Please leave query unanswered until information is available or, if unable to obtain, please state so. '	Jennifer Molstead (b) (4)	14 Mar 2021 16:29:58
answered with 'updated' (Site from Safety).		
DataPoint Un-verified.	Jennifer Molstead (b) (4)	14 Mar 2021 16:29:44
User entered 'LUMP WAS DISCOVERED ON MAMMOGRAM PERFORMED 23OCT2020. DUCTAL CARCINOMA INSITU RIGHT BREAST WAS DIAGNOSED 19NOV2020. SUBJECT HAD LUMPECTOMY 23DEC2020. Subjects pathology showed Lobular Carcinoma in situ' reason for change: New Information	Jennifer Molstead (b) (4)	14 Mar 2021 16:29:44
User closed query 'Per DM CLR: SAE Narrative = MAMMOGRAM PERFORMED 23OCT2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. '	(b) (4), (b) (6)	28 Jan 2021 04:16:25
(Site from DM).		

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:30:30

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = MAMMOGRAM PERFORMED 23OCT2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Mammogram has been added to ConProc.' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	27 Jan 2021 15:15:21
User opened query 'PV Query: Please provide lumpectomy pathology results. Please leave query unanswered until information is available or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 18:44:59
User opened query 'PV Query: Please provide any additional relevant labs and diagnostic test results. Please leave query unanswered until information is available or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 18:44:44
User opened query 'Per DM CLR: SAE Narrative = MAMMOGRAM PERFORMED 23OCT2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 11:15:17
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:37:02
User closed query 'PV Query: Please provide lumpectomy pathology results.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 17:32:22
User closed query 'PV Query: Please provide any additional relevant labs and diagnostic test results.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 17:32:18
Query 'PV Query: Please provide lumpectomy pathology results.' answered with 'RECORDS HAVE NOT BEEN RECEIVED AS OF YET.' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	19 Jan 2021 22:23:17
Query 'PV Query: Please provide any additional relevant labs and diagnostic test results.' answered with 'RECORDS HAVE NOT BEEN RECEIVED AS OF YET.' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	19 Jan 2021 22:23:14
User opened query 'PV Query: Please provide lumpectomy pathology results.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 14:50:28
User opened query 'PV Query: Please provide any additional relevant labs and diagnostic test results.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 14:50:14

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide lumpectomy pathology results.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 14:53:56
User closed query 'PV Query: Please provide any additional relevant labs and diagnostic test results.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 14:53:53
Query 'PV Query: Please provide lumpectomy pathology results.' answered with 'Awaiting records' (Site from Safety).	Jennifer Molstead (b) (4)	08 Jan 2021 22:51:49
Query 'PV Query: Please provide any additional relevant labs and diagnostic test results.' answered with 'Awaiting Records' (Site from Safety).	Jennifer Molstead (b) (4)	08 Jan 2021 22:51:40
User opened query 'PV Query: Please provide lumpectomy pathology results.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 16:41:19
User opened query 'PV Query: Please provide any additional relevant labs and diagnostic test results.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 16:41:08
User entered 'Lump was discovered on Mammogram performed 23Oct2020. Ductal Carcinoma Insitu Right breast was diagnosed 19Nov2020. Subject had lumpectomy 23Dec2020. Awaiting rest of medical records.'	Jennifer Molstead (b) (4)	29 Dec 2020 20:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Dec 2020 20:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Dec 2020 20:05:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:30:30

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User closed query 'Concomitant Medications were entered. Please consider updating the response to "Yes" if applicable.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:20:39
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 21:20:35
Query 'Concomitant Medications were entered. Please consider updating the response to "Yes" if applicable.' answered with 'data updated' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 17:05:30
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 17:05:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 17:05:16
User closed query 'Per ETRTR: Please confirm no medication was dosed for Lumpectomy performed on 23Dec20. If dosed, please ensure to update SAE page for Concomitant Medication action taken, thanks.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 18:03:03
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:02:58
User opened query 'Concomitant Medications were entered. Please consider updating the response to "Yes" if applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 18:00:54
Query 'Per ETRTR: Please confirm no medication was dosed for Lumpectomy performed on 23Dec20. If dosed, please ensure to update SAE page for Concomitant Medication action taken, thanks.' answered with 'No medications were taken for lumpectomy.' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	20 Jan 2021 13:50:26
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Jan 2021 13:50:23
User opened query 'Per ETRTR: Please confirm no medication was dosed for Lumpectomy performed on 23Dec20. If dosed, please ensure to update SAE page for Concomitant Medication action taken, thanks.' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 15:17:28
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:33:31

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:19
User coded data point as ATC: VARIOUS, ATC: ALLERGENS, ATC: ALLERGENS, ATC: ALLERGEN EXTRACTS, PRODUCT: ALLERGENS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 17:45:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 17:45:59
Data point term sent to Coder	System	04 Aug 2020 17:42:04
User entered 'ALLERGY SHOTS: RAGWEED AND MOLD'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:41:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:21
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:41:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:41:22
User entered 'ENVIRONMENTAL ALLERGIES'	Tarin Gordon (b) (4)	04 Aug 2020 17:41:14
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:41:25
User entered 'I'	Tarin Gordon (b) (4)	04 Aug 2020 17:41:14
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:26
User entered 'Other (OTHER)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:41:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:28
User entered 'SHOT'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:41:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:31
User entered 'every month (QM)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:41:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:36
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:41:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:38
User entered 'Intramuscular (INTRAMUSCULAR)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:41:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:30

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:40
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:41:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:41:43
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:26:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	04 Aug 2020 18:16:12
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'UN UNK 2018'	System	04 Aug 2020 17:41:14
	Tarin Gordon (b) (4)	04 Aug 2020 17:41:14
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:41:46
User entered '0'	Tarin Gordon (b) (4)	04 Aug 2020 17:41:14
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:48
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:41:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:50
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 17:41:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:41:52
User entered 'No (N)'	Tarin Gordon (b) (4)	04 Aug 2020 17:41:14
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 17:41:14

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 17:41:14

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:30:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	04 Aug 2020 17:41:14

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: BIMATOPROST - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Jan 2021 17:02:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 17:02:01
Data point term sent to Coder	System	22 Jan 2021 17:01:48
Data point term sent to Coder	System	22 Jan 2021 16:59:46
Coding entries removed.	Tammy Kohn (b) (4)	22 Jan 2021 16:59:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:58
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: BIMATOPROST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 14:31:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 14:31:39
Data point term sent to Coder	System	07 Jan 2021 21:21:33
Coding entries removed.	Tammy Kohn (b) (4)	07 Jan 2021 21:21:29
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: BIMATOPROST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 12:42:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 12:42:33
Data point term sent to Coder	System	26 Oct 2020 12:04:06
Coding entries removed.	Tammy Kohn (b) (4)	26 Oct 2020 12:03:46

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: BIMATOPROST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 21:19:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 21:19:47
Data point term sent to Coder Coding entries removed.	System	24 Sep 2020 12:46:01
	Tammy Kohn (b) (4)	24 Sep 2020 12:45:36
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PROSTAGLANDIN ANALOGUES, PRODUCT: BIMATOPROST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 19:46:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 19:46:58
Data point term sent to Coder	System	04 Aug 2020 18:17:31
User entered 'BIMATOPROST'	Tarin Gordon (b) (4)	04 Aug 2020 18:17:28

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:59
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:17:28

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:42:02
User closed query 'Per DM CLR: Please update the indication to reflect the location if Left, Right, or Bilateral. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 17:08:02
Query 'Per DM CLR: Please update the indication to reflect the location if Left, Right, or Bilateral. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'DATA UPDATED GLAUCOMA BILATERAL' (Site from DM).	Tammy Kohn (b) (4)	24 Sep 2020 12:45:45
	(b) (4)	
User entered 'GLAUCOMA BILATERAL' reason for change: Data Entry Error	Tammy Kohn (b) (4)	24 Sep 2020 12:45:36
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the location if Left, Right, or Bilateral. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 11:59:47
User entered 'GLAUCOMA'	Tarin Gordon (b) (4)	04 Aug 2020 18:17:28
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:59:19
User closed query 'Per DM CLR: Please provide the strength of this medication in the medication name, and consider recording the number of drops instead (e.g. Dose = 1; Unit = Drops). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 13:09:38
Query 'Per DM CLR: Please provide the strength of this medication in the medication name, and consider recording the number of drops instead (e.g. Dose = 1; Unit = Drops). Review and amend as appropriate.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	07 Jan 2021 21:21:36
User entered '1' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 21:21:29
User opened query 'Per DM CLR: Please provide the strength of this medication in the medication name, and consider recording the number of drops instead (e.g. Dose = 1; Unit = Drops). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 13:15:51
User entered '0.1'	Tarin Gordon (b) (4)	04 Aug 2020 18:17:28
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User closed query 'Per the DM CLR query, please update "mL" to "Drop".' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:19:42
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 21:19:12
Query 'Per the DM CLR query, please update "mL" to "Drop".' answered with 'data updated' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 17:01:02
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 16:59:26
User entered 'Other (OTHER)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 16:59:26
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:44:38
User opened query 'Per the DM CLR query, please update "mL" to "Drop".' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 17:44:36
User closed query 'Per DM CLR: Please note 0.1 MG/ML is the strength rather than the dose. Please provide the strength of this medication in the medication name, and consider recording the number of drops instead (e.g. dose=1; unit=drops). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:39:29
Query 'Per DM CLR: Please note 0.1 MG/ML is the strength rather than the dose. Please provide the strength of this medication in the medication name, and consider recording the number of drops instead (e.g. dose=1; unit=drops). Review and amend as appropriate.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	26 Oct 2020 12:04:32
User entered 'mL (mL)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	26 Oct 2020 12:04:20
User opened query 'Per DM CLR: Please note 0.1 MG/ML is the strength rather than the dose. Please provide the strength of this medication in the medication name, and consider recording the number of drops instead (e.g. dose=1; unit=drops). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 12:33:41
User entered 'Other (OTHER)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:17:28

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 21:19:11
DataPoint Un-verified.	Tammy Kohn (b) (4)	22 Jan 2021 16:59:26
	(b) (4)	
User entered 'drop' reason for change: Data Entry Error	Tammy Kohn (b) (4)	22 Jan 2021 16:59:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:44:49
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	26 Oct 2020 12:04:20
	(b) (4)	
User entered 'MG/ML'	Tarin Gordon (b) (4)	04 Aug 2020 18:17:28
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:44:51
User entered 'once daily (QD)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:17:28

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:44:53
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:17:28

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 21:19:14
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	22 Jan 2021 17:01:18
User entered 'Other (OTHER)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	22 Jan 2021 17:01:18
	(b) (4)	
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	22 Jan 2021 16:59:26
DataPoint Un-verified.	Tammy Kohn (b) (4)	22 Jan 2021 16:59:26
	(b) (4)	
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	22 Jan 2021 16:59:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:44:55
User entered 'Other (OTHER)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	07 Jan 2021 21:21:29
	(b) (4)	
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate (eg. Topical).' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:03:12
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate (eg. Topical).' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	26 Oct 2020 12:04:36
	(b) (4)	
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	26 Oct 2020 12:03:46
	(b) (4)	
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate (eg. Topical).' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 12:33:53
User entered 'Intraocular (INTRAOCULAR)'	Tarin Gordon (b) (4)	04 Aug 2020 18:17:28
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
	(b) (4)	
User closed query 'Consider "Topical".' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 19:04:42
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 19:04:32
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 21:19:50
Query 'Consider "Topical".' answered with 'data updated' (Site from CRA).	Tammy Kohn (b) (4)	22 Jan 2021 17:01:05
	(b) (4)	
User opened query 'Consider "Topical".' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 17:48:52
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:44:59
User entered 'DROP' reason for change: Data Entry Error	Tammy Kohn (b) (4)	07 Jan 2021 21:21:29
	(b) (4)	
User entered empty.	Tarin Gordon (b) (4)	04 Aug 2020 18:17:28
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:45:08
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:26:18
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	04 Aug 2020 18:21:13
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'UN UNK 2011'	System	04 Aug 2020 18:17:28
	Tarin Gordon (b) (4)	04 Aug 2020 18:17:28
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:45:29
User entered '0'	Tarin Gordon (b) (4)	04 Aug 2020 18:17:28
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:45:30
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:17:28

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:45:32
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:17:28

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:45:34
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:17:28

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 18:17:28

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 18:17:28

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:30:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 18:17:28

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:50:14
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: CARBONIC ANHYDRASE INHIBITORS, PRODUCT: BRIMONIDINE TARTRATE;BRINZOLAMIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 14:39:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 14:39:43
Data point term sent to Coder Coding entries removed.	System Tammy Kohn (b) (4) (b) (4)	26 Oct 2020 12:05:06 26 Oct 2020 12:04:58
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: CARBONIC ANHYDRASE INHIBITORS, PRODUCT: BRIMONIDINE TARTRATE;BRINZOLAMIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 04:16:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 04:16:35
Data point term sent to Coder Coding entries removed.	System Tammy Kohn (b) (4) (b) (4)	24 Sep 2020 12:46:01 24 Sep 2020 12:45:58
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: CARBONIC ANHYDRASE INHIBITORS, PRODUCT: BRIMONIDINE TARTRATE;BRINZOLAMIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 23:39:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 23:39:03
Data point term sent to Coder	System	04 Aug 2020 18:19:32

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'brinzolamide/brimonidine tartrate'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:19:29

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:50:15
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:19:29

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:50:17
User closed query 'Per DM CLR: Please update the indication to reflect the location if Left, Right, or Bilateral. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 17:08:05
Query 'Per DM CLR: Please update the indication to reflect the location if Left, Right, or Bilateral. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'GLAUCOMA BILATERAL' (Site from DM).	Tammy Kohn (b) (4)	24 Sep 2020 12:46:02
	(b) (4)	
User entered 'GLAUCOMA BILATERAL' reason for change: Data Entry Error	Tammy Kohn (b) (4)	24 Sep 2020 12:45:58
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the location if Left, Right, or Bilateral. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 12:02:26
User entered 'GLAUCOMA'	Tarin Gordon (b) (4)	04 Aug 2020 18:19:29
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:50:18
User entered '2'	Tarin Gordon (b) (4)	04 Aug 2020 18:19:29
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:50:20
User entered 'Other (OTHER)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:19:29

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:50:22
User entered 'DROPS'	Tarin Gordon (b) (4)	04 Aug 2020 18:19:29
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:50:23
User entered 'once daily (QD)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:19:29

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:50:25
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:19:29

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:50:27
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate (eg. Topical).' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:03:24
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate (eg. Topical).' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	26 Oct 2020 12:05:04
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 12:04:58
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate (eg. Topical).' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 12:34:17
User entered 'Intraocular (INTRAOCULAR)'	Tarin Gordon (b) (4)	04 Aug 2020 18:19:29
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:50:29
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:19:29

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:50:30
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:26:28
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	04 Aug 2020 18:21:07
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'UN UNK 2011'	System	04 Aug 2020 18:19:29
	Tarin Gordon (b) (4)	04 Aug 2020 18:19:29
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:50:32
User entered '0'	Tarin Gordon (b) (4)	04 Aug 2020 18:19:29
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:50:33
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:19:29

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:50:35
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:19:29

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:50:36
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:19:29

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 18:19:29

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 18:19:29

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:30:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 18:19:29

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:50:46
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.	Coder Import (b) (4)	04 Aug 2020 18:22:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 18:22:09
Data point term sent to Coder	System	04 Aug 2020 18:20:33
User entered 'MULTIVITAMIN'	Tarin Gordon (b) (4)	04 Aug 2020 18:20:03
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:50:44
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:20:03

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:50:48
User entered 'SUPPLEMENT'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:20:03

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:50:49
User entered 'I'	Tarin Gordon (b) (4)	04 Aug 2020 18:20:03
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:50:51
User entered 'tablet (TABLET)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:20:03

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:50:53
User entered empty.	Tarin Gordon (b) (4)	04 Aug 2020 18:20:03
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:50:55
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	04 Aug 2020 18:20:03
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:50:56
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:20:03

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:50:58
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:20:03

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:51:00
User entered empty.	Tarin Gordon (b) (4)	04 Aug 2020 18:20:03
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:51:04
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:26:34
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	04 Aug 2020 18:21:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'UN UNK 2016'	System	04 Aug 2020 18:20:03
	Tarin Gordon (b) (4)	04 Aug 2020 18:20:03
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:51:06
User entered '0'	Tarin Gordon (b) (4)	04 Aug 2020 18:20:03
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:51:08
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:20:03

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:51:11
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:20:03

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:51:13
User entered 'No (N)'	Tarin Gordon (b) (4)	04 Aug 2020 18:20:03
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 18:20:03

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 18:20:03

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:30:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 18:20:03

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:51:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 18:22:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 18:22:09
Data point term sent to Coder	System	04 Aug 2020 18:20:33
User entered 'VITAMIN D'	Tarin Gordon (b) (4)	04 Aug 2020 18:20:33
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:51:20
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:20:33

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:53:55
User entered 'SUPPLEMENT'	Tarin Gordon (b) (4)	04 Aug 2020 18:20:33
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:53:57
User entered '125'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:20:33

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:53:58
User entered 'ug (ug)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:20:33

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:57:19
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:20:33

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:54:12
User entered 'once daily (QD)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:20:33

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:54:14
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:20:33

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:54:17
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	04 Aug 2020 18:20:33
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:54:18
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:20:33

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:54:20
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:26:41
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Tarin Gordon (b) (4)	04 Aug 2020 18:20:53
answered with 'ONGOING' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 18:20:33
User entered 'UN UNK 2016'	Tarin Gordon (b) (4)	04 Aug 2020 18:20:33
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:54:22
User entered '0'	Tarin Gordon (b) (4)	04 Aug 2020 18:20:33
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:54:25
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:20:33

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:54:26
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:20:33

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:54:28
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 18:20:33

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 18:20:33

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 18:20:33

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:30:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 18:20:33

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:55:30
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:49:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:49:40
Data point term sent to Coder	System	02 Nov 2020 21:58:35
User entered 'influenza vaccine'	Abigail Wine (b) (4) (b) (4)	02 Nov 2020 21:58:18

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:55:31
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	02 Nov 2020 21:58:18

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:55:33
User entered 'influenza prophylaxis'	Abigail Wine (b) (4) (b) (4)	02 Nov 2020 21:58:18

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:55:34
User entered '0.5'	Abigail Wine (b) (4) (b) (4)	02 Nov 2020 21:58:18

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:55:41
User entered 'mL (mL)'	Abigail Wine (b) (4) (b) (4)	02 Nov 2020 21:58:18

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:55:42
User entered empty.	Abigail Wine (b) (4) (b) (4)	02 Nov 2020 21:58:18

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:55:44
User entered 'once (ONCE)'	Abigail Wine (b) (4) (b) (4)	02 Nov 2020 21:58:18

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:55:45
User entered empty.	Abigail Wine (b) (4) (b) (4)	02 Nov 2020 21:58:18

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:55:47
User entered 'Intramuscular (INTRAMUSCULAR)'	Abigail Wine (b) (4) (b) (4)	02 Nov 2020 21:58:18

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:30

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:55:48
User entered empty.	Abigail Wine (b) (4) (b) (4)	02 Nov 2020 21:58:18

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:55:39
User entered '19 Oct 2020'	Abigail Wine (b) (4) (b) (4)	02 Nov 2020 21:58:18

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:55:50
User entered '0'	Abigail Wine (b) (4) (b) (4)	02 Nov 2020 21:58:18

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:55:52
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	02 Nov 2020 21:58:18

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:55:53
User entered '19 Oct 2020'	Abigail Wine (b) (4)	02 Nov 2020 21:58:18

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:03
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:55:55
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	02 Nov 2020 21:58:18

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:03
User entered empty.	System	02 Nov 2020 21:58:18

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:03
User entered empty.	System	02 Nov 2020 21:58:18

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:30:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:12:03
User entered empty.	System	02 Nov 2020 21:58:18

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:56:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 13:26:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 13:26:42
Data point term sent to Coder	System	16 Nov 2020 13:26:20
User entered 'KEFLEX'	Tammy Kohn (b) (4)	16 Nov 2020 13:25:57
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:56:35
User entered 'No (N)'	Tammy Kohn (b) (4)	16 Nov 2020 13:25:57
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:56:37
User entered 'URINARY TRACT INFECTION'	Tammy Kohn (b) (4)	16 Nov 2020 13:25:57
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:56:39
User entered '500'	Tammy Kohn (b) (4)	16 Nov 2020 13:25:57
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:56:40
User entered 'mg (mg)'	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 13:25:57

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:56:42
User entered empty.	Tammy Kohn (b) (4)	16 Nov 2020 13:25:57
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:56:44
User entered 'three times daily (TID)'	Tammy Kohn (b) (4)	16 Nov 2020 13:25:57
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:56:46
User entered empty.	Tammy Kohn (b) (4)	16 Nov 2020 13:25:57
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:56:47
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4)	16 Nov 2020 13:25:57
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:56:49
User entered empty.	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 13:25:57

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:56:50
User entered '7 Nov 2020'	Tammy Kohn (b) (4)	16 Nov 2020 13:25:57
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:56:52
User entered '0'	Tammy Kohn (b) (4)	16 Nov 2020 13:25:57
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:56:55
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 13:25:57

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:56:56
User entered empty.	Tammy Kohn (b) (4)	16 Nov 2020 13:25:57
	(b) (4)	

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:56:58
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 14:20:54
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	08 Jan 2021 19:20:09
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	08 Jan 2021 19:20:01
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	08 Jan 2021 19:19:19
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	08 Jan 2021 17:47:32
	(b) (4)	
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 13:16:30

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 13:25:57

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Nov 2020 13:25:57

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 13:25:57

US3402211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:30:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Nov 2020 13:25:57

US3402211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:30:30

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:40
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:46:21
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Jennifer Molstead (b) (4)	29 Dec 2020 20:06:22
User entered 'No (N)'	(b) (4)	
	Traci Hull (b) (4)	03 Sep 2020 20:50:28
	(b) (4)	

US3402211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:30:30

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:38:55
User entered '19 Nov 2020'	Jennifer Molstead (b) (4)	29 Dec 2020 20:06:50
	(b) (4)	

US3402211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:30:30

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:38:58
User entered 'Right Breast Biopsy'	Jennifer Molstead (b) (4)	29 Dec 2020 20:06:50
	(b) (4)	

US3402211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:30:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:39:00
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4)	29 Dec 2020 20:06:50
	(b) (4)	

US3402211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:30:30

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 17:39:02
User entered empty.	Jennifer Molstead (b) (4)	29 Dec 2020 20:06:50
	(b) (4)	

US3402211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:30:30

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:27:14
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 17:38:43
User entered '23 Dec 2020'	Jennifer Molstead (b) (4)	29 Dec 2020 20:07:21

US3402211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:30:30

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:27:14
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:38:44
User entered 'Right Breast lumpectomy'	Jennifer Molstead (b) (4) (b) (4)	29 Dec 2020 20:07:21

US3402211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:30:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:27:14
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4)	29 Dec 2020 20:07:21
	(b) (4)	

US3402211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:30:30

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:27:14
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Jennifer Molstead (b) (4)	29 Dec 2020 20:07:21
	(b) (4)	

US3402211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:30:30

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:27:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:46:09
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered '23 Oct 2020'	(b) (4) Tammy Kohn (b) (4)	27 Jan 2021 15:05:47

US3402211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:30:30

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:27:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:46:10
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Mammogram'	(b) (4) Tammy Kohn (b) (4) (b) (4)	27 Jan 2021 15:05:47

US3402211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:30:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:27:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:46:12
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Diagnostic (DIAGNOSTIC)'	Tammy Kohn (b) (4)	27 Jan 2021 15:05:47

US3402211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:30:30

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:27:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:46:14
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered empty.	(b) (4) Tammy Kohn (b) (4)	27 Jan 2021 15:05:47

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered	System	30 Dec 2020 15:15:14
'USA-US059-2020-MRNA-1273-P301000026'		

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Yes (Y)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Yes (Y)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Frank'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Eder'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered '1290 Upper Front Street'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Binghamton'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'NY'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered '13901'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 18:47:27
User entered 'US'	System	30 Dec 2020 15:15:42

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	15 Mar 2021 14:25:06
User entered '3'	System	20 Jan 2021 17:33:50
User entered '2'	System	07 Jan 2021 18:47:39
User entered '1'	System	30 Dec 2020 15:15:42

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered		
'USA-US059-2020-MRNA-1273-P301000026'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Yes (Y)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Yes (Y)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Frank'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Eder'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered '1290 Upper Front Street'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Binghamton'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'NY'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered '13901'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 18:47:27
User entered 'US'	System	30 Dec 2020 15:15:42

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	15 Mar 2021 14:25:06
User entered '3'	System	20 Jan 2021 17:33:50
User entered '2'	System	07 Jan 2021 18:47:39
User entered '1'	System	30 Dec 2020 15:15:42

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:30:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:04:32
User entered '30/Dec/2020 15:15'	System	30 Dec 2020 15:15:42

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:30:30

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.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 18:47:27
User entered 'I'	(b) (4), (b) (6)	30 Dec 2020 15:15:42

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered		
'USA-US059-2020-MRNA-1273-P301000026'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Yes (Y)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Yes (Y)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Frank'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Eder'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered '1290 Upper Front Street'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Binghamton'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'NY'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered '13901'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 18:47:27
User entered 'US'	System	30 Dec 2020 15:15:42

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	15 Mar 2021 14:25:06
User entered '3'	System	20 Jan 2021 17:33:50
User entered '2'	System	07 Jan 2021 18:47:39
User entered '1'	System	30 Dec 2020 15:15:42

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:30:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:04:32
User entered '07/Jan/2021 18:47'	System	07 Jan 2021 18:47:39

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:30:30

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.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 17:33:53
User entered 'I'	(b) (4), (b) (6)	07 Jan 2021 18:47:39

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered	System	30 Dec 2020 15:15:14
'USA-US059-2020-MRNA-1273-P301000026'		

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Yes (Y)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Yes (Y)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Frank'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Eder'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered '1290 Upper Front Street'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Binghamton'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'NY'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered '13901'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 18:47:27
User entered 'US'	System	30 Dec 2020 15:15:42

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	15 Mar 2021 14:25:06
User entered '3'	System	20 Jan 2021 17:33:50
User entered '2'	System	07 Jan 2021 18:47:39
User entered '1'	System	30 Dec 2020 15:15:42

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:30:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:04:32
User entered '20/Jan/2021 12:33'	System	20 Jan 2021 17:33:50

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:30:30

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.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 17:33:53
User entered 'I'	(b) (4), (b) (6)	20 Jan 2021 17:33:50

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered	System	30 Dec 2020 15:15:14
'USA-US059-2020-MRNA-1273-P301000026'		

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Yes (Y)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

Generated On: 09 Jun 2021 17:30:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

US3402211

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'No (N)'	System	30 Dec 2020 15:15:14

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Yes (Y)'	System	30 Dec 2020 15:15:14

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Frank'	System	30 Dec 2020 15:15:14

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Eder'	System	30 Dec 2020 15:15:14

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[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered '1290 Upper Front Street'	System	30 Dec 2020 15:15:14

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[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'Binghamton'	System	30 Dec 2020 15:15:14

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[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered 'NY'	System	30 Dec 2020 15:15:14

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 15:15:35
User entered '13901'	System	30 Dec 2020 15:15:14

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:04:32
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 18:47:27
User entered 'US'	System	30 Dec 2020 15:15:42

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	15 Mar 2021 14:25:06
User entered '3'	System	20 Jan 2021 17:33:50
User entered '2'	System	07 Jan 2021 18:47:39
User entered '1'	System	30 Dec 2020 15:15:42

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Folder: SAE USA-US059-2020-MRNA-1273-P301000026

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:30:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 17:48:50
User entered '15/Mar/2021 07:25'	System	15 Mar 2021 14:25:06

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Form: Safety Report Form (4)

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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.	Frank Eder (b) (4)	26 Apr 2021 22:49:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 17:48:53
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 14:25:06