

US3442068 (Prod: Benchmark Research - Fort Worth)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:40:54

All time stamps listed in this document are displayed in GMT

US3442068

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 18:54:42

Generated On: 09 Jun 2021 17:40:54

[Participant ID](#)

US3442068

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

US3442068

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	59
Age Units	YEARS
Age (Derived)	59
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Condition	ACID REFLUX
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)	_____

US3442068

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3442068

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3442068

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

US3442068

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Condition	MILD DEPRESSION
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) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Condition	ANXIETY
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)	_____

US3442068

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Condition	OSTEOATHRITIS (BILATERAL KNEES AND SHOULDERS, NECK)
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) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Condition	MIGRAINES
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)	

US3442068

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Condition	NEUROPATHY IN THE LEFT ARM
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)	

US3442068

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Condition	TWO DEGENERATIVE CERVICAL DISCS
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	30 DEC 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	DEC 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:48 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 16:48
Height (<i>xxx.x</i>)	66 in
Weight (<i>xxx.x</i>)	166.2 lb
BMI (<i>xxx.x</i>)	26.88147 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) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:54:43

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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

GOVERNMENT POSITION

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) 23 Feb 2021 18:54:43

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

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

What was the participant's randomization number? 144628

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☒
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☒ No ☐

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

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) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	16:48 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 16:48
Temperature (xxx.x)	96.9 F
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)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	19:10 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 19:10
Temperature (xxx.x)	96.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 18:37 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 18:37

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) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 AUG 2020

Collection time (00:00-23:59)

17:49 (24 HR)

Collection date and time (derived)

21 AUG 2020 17:49

US3442068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:45	21 AUG 2020 17:45
Nasopharyngeal Swab 2	No		

US3442068

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 19:07

PC Open Date & Time

21 AUG 2020 18:57

PC Close Date & Time

21 AUG 2020 21:27

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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 97.2 °F

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

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

PC Time Stamp	22 AUG 2020 11:52
PC Open Date & Time	21 AUG 2020 22:22
PC Close Date & Time	22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °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

23 AUG 2020 11:24

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °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

24 AUG 2020 11:24

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:54

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 07:44

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:54

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 09:06

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:54

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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 09:34

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 09:31

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 19:07

PC Open Date & Time

21 AUG 2020 18:57

PC Close Date & Time

21 AUG 2020 21:27

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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

5

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 11:54

PC Open Date & Time

21 AUG 2020 22:22

PC Close Date & Time

22 AUG 2020 11:59

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

3

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

23 AUG 2020 11:25

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

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

2

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

24 AUG 2020 11:25

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

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

1

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

25 AUG 2020 07:45

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:54

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

26 AUG 2020 09:06

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:54

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

27 AUG 2020 09:35

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:54

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

28 AUG 2020 09:31

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 19:08
PC Open Date & Time	21 AUG 2020 18:57
PC Close Date & Time	21 AUG 2020 21:27

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 11:54
PC Open Date & Time	21 AUG 2020 22:22
PC Close Date & Time	22 AUG 2020 11:59

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

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 ☒

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 11:25
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

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)

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 11:25
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

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 ☒

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 07:46
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 2030

EAB) (1725)

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 09:06
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

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 ☒

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 09:35
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

61 of 2030

EAB) (1725)

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 09:31
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3442068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442068

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442068

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442068

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:54:44

Generated On: 09 Jun 2021 17:40:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:54:44

Generated On: 09 Jun 2021 17:40:54

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)	22 SEP 2020
Time of assessment (00:00-23:59)	07:28 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 07:28
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:54:44

Generated On: 09 Jun 2021 17:40:54

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)	22 SEP 2020
Time of assessment (00:00-23:59)	09:45 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 09:45
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3442068

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:54:44

Generated On: 09 Jun 2021 17:40:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3442068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

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) 22 SEP 2020

What was the treatment time? (00:00-23:59) 08:57 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 08:57

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

US3442068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:54:44

Generated On: 09 Jun 2021 17:40:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 SEP 2020

Collection time (00:00-23:59)

07:52 (24 HR)

Collection date and time (derived)

22 SEP 2020 07:52

US3442068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:55	22 SEP 2020 07:55
Nasopharyngeal Swab 2	No		

US3442068

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 09:46

PC Open Date & Time

22 SEP 2020 09:17

PC Close Date & Time

22 SEP 2020 11:47

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 20:49

PC Open Date & Time

22 SEP 2020 12:42

PC Close Date & Time

23 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:54

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

23 SEP 2020 12:37

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

24 SEP 2020 22:43

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 19:56

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:54

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 17:04

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

27 SEP 2020 20:54

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:54

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 13:18

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 09:47

PC Open Date & Time

22 SEP 2020 09:17

PC Close Date & Time

22 SEP 2020 11:47

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

5

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)**

5

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 21:04

PC Open Date & Time

22 SEP 2020 12:42

PC Close Date & Time

23 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

5

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

23 SEP 2020 12:38

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

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

3

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

25 SEP 2020 05:20

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

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

1

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

25 SEP 2020 19:57

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:54

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

26 SEP 2020 17:05

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:54

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

27 SEP 2020 20:55

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:54

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

28 SEP 2020 13:18

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 09:48
PC Open Date & Time	22 SEP 2020 09:17
PC Close Date & Time	22 SEP 2020 11:47

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 21:05
PC Open Date & Time	22 SEP 2020 12:42
PC Close Date & Time	23 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

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 ☒

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 12:38
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

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 ☒

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 05:20
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

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 ☒

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 19:58
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

103 of 2030

EAB) (1725)

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 17:05
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

105 of 2030

EAB) (1725)

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 20:55
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

107 of 2030

EAB) (1725)

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 13:18
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3442068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442068

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442068

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442068

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442068

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442068

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:54:44

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:54:44

Generated On: 09 Jun 2021 17:40:54

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3442068

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:54:44

Generated On: 09 Jun 2021 17:40:54

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.

US3442068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:54:44

Generated On: 09 Jun 2021 17:40:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 OCT 2020
Collection time (00:00-23:59)	08:45 (24 HR)
Collection date and time (derived)	19 OCT 2020 08:45

US3442068

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:54:44

Generated On: 09 Jun 2021 17:40:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 OCT 2020 18:04:20
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

04 NOV 2020 11:03:47

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 NOV 2020 12:51:26
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 11:11:10
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 16:16:58

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 09:44:29

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	15 DEC 2020 13:12:07
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

21 DEC 2020 17:12:24

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 07:12:41

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

07 JAN 2021 10:56:38

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

10 JAN 2021 06:46:35

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 07:09:18

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 00:02:18

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 <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"/>

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 173

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

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

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

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

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

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

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 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"/>

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 17:10:09

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 MAR 2021 22:33:52
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

22 MAR 2021 18:30:20

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 222

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

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 229

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

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☒

Yes ☐

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

15 APR 2021 12:54:56

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

20 APR 2021 05:54:21

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

27 APR 2021 22:38:45

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 257

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

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

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

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

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

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

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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"/>

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 334

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

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

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

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

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

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

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

Patient Cloud Open Date & Time	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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"/>

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

Patient Cloud Open Date & Time	03 OCT 2021 00:01
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Patient Cloud Close Date & Time	07 OCT 2021 23:59
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US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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"/>

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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"/>

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

Patient Cloud Open Date & Time	05 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

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03 MAR 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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"/>

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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="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"/>

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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"/>

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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"/>

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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"/>

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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"/>

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

Patient Cloud Open Date & Time	14 AUG 2022 00:01
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Patient Cloud Close Date & Time	18 AUG 2022 23:59
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US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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"/>

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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"/>

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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"/>

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3442068

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:40:54

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		08 MAR 2021 17:10:29

US3442068

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442068

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442068

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442068

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442068

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442068

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442068

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442068

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:32:25

Generated On: 09 Jun 2021 17:40:54

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

Visit date (dd MMM yyyy)	11 MAR 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	VISIT4
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US3442068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3442068

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:32:25

Generated On: 09 Jun 2021 17:40:54

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.

US3442068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 21:32:25

Generated On: 09 Jun 2021 17:40:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 MAR 2021

Collection time (00:00-23:59)

09:33 (24 HR)

Collection date and time (derived)

11 MAR 2021 09:33

US3442068

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:32:25

Generated On: 09 Jun 2021 17:40:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442068

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3442068

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:40:54

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"/>

US3442068

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:40:54

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3442068

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:54:43

Generated On: 09 Jun 2021 17:40:54

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

Visit date (dd MMM yyyy)	18 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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US3442068

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

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:32:25

Generated On: 09 Jun 2021 17:40:54

Date of updated informed consent (dd MMM yyyy) 18 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 18 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3442068

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:54:42

Generated On: 09 Jun 2021 17:40:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 JAN 2021

Collection time (00:00-23:59)

09:46 (24 HR)

Collection date and time (derived)

18 JAN 2021 09:46

US3442068

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 18:54:42

Generated On: 09 Jun 2021 17:40:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00 - 23:59)	09:44
Collection Date and Time (derived)	18 JAN 2021 09:44

US3442068

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 18:54:42

Generated On: 09 Jun 2021 17:40:54

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3442068

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Mar 2021 21:32:25

Generated On: 09 Jun 2021 17:40:54

AEID	USA-US017-2021-MRNA-1273-P30 1000006
Adverse event	CERVICAL SPONDYLOSIS WITH RADICULOPATHY
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)	30 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	30 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	31 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Mar 2021 21:32:25

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Mar 2021 21:32:25

Generated On: 09 Jun 2021 17:40:54

SUBJECT HAS SUFFERED FROM
2 DEGENERATIVE CERVICAL
DISC FOR SEVERAL YEARS,
THIS WAS PREVIOUSLY
DOCUMENTED AS MEDICAL
HISTORY. SURGERY SERVES AS
TREATMENT FOR THIS LONG
TIME DIAGNOSIS.

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

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 18:54:42

Generated On: 09 Jun 2021 17:40:54

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

Yes ☒

No ☐

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

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS: NECK,
BILATERALLY SHOULDERS
AND KNEES

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Name of Medication CITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION/ANXIETY

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

	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 2019
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) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication NEUROPATHY: LEFT ARM

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

	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 2019	
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) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Name of Medication FENOFIBRATE

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 2.5

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 (5)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

	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 2019	
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) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Name of Medication HYDROCHLORATHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 850

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Name of Medication TOPIRAMATE

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Name of Medication SUMATRIPTAN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

	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 2019	
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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication ACID REFLUX

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

	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 2019	
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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication CERVICAL REPLACEMENT AND
FUSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 8 HOURS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

	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)		30 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Name of Medication ACETAMINOPHEN-CODEINE

Prophylaxis Yes ☐
No ☒

Indication APPENDICITIS

Dose per administration 300/30

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

EVERY 4 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

	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)		30 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐
No ☒

Indication APPENDICITIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

362 of 2030

EAB) (1725)

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

	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)		30 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Name of Medication JARDIANCE

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

364 of 2030

EAB) (1725)

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

Name of Medication VITAMIN D 3

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 2000

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

366 of 2030

EAB) (1725)

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3442068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 18:54:42

Generated On: 09 Jun 2021 17:40:54

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3442068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Feb 2021 18:54:42

Generated On: 09 Jun 2021 17:40:54

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
30 DEC 2020	CERVICAL REPLACEMENT AND FUSION TWO DEGENERATIVE CERVICAL DISC	Adverse Event	

US3442068

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:40:54

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

US3442068

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:40:54

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 ☐

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

SAEID	USA-US017-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

SAEID	USA-US017-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	20/JAN/2021 17:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 13 Apr 2021 15:19:28

Generated On: 09 Jun 2021 17:40:54

SAEID	USA-US017-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SEGER
Site Address: Street	4504 BOAT CLUB ROAD, SUITE 400A
Site Address: City	FORT WORTH
Site Address: State	
Site Address: Postal Code	76135
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	05/MAR/2021 12:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3442068 (Prod: Benchmark Research - Fort Worth)

US3442068

Form: Participant Creation

Generated On: 09 Jun 2021 17:40:54

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 04:26:23
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'US3442068'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 21:24:21

US3442068

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:25:39
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:41:14

US3442068

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:25:44
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 21:24:22

US3442068

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

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 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:17:47
User closed query 'Source does not reflect this visit type as clinic visit. Please update the source and make the changes in this field accordingly. ' (Site from CRA).		10 Dec 2020 20:17:45
Query 'Source does not reflect this visit type as clinic visit. Please update the source and make the changes in this field accordingly. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	10 Dec 2020 20:17:27
User opened query 'Source does not reflect this visit type as clinic visit. Please update the source and make the changes in this field accordingly. ' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 18:07:44
User entered 'Clinic (Clinic)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:41:14

US3442068

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'SCRN'	System	21 Aug 2020 23:41:14

US3442068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:54

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:27:43
User entered (b) (6) 1961'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 21:24:23

US3442068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:54

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:27:46
User entered '59'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:10

US3442068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:54

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'YEARS'	System	21 Aug 2020 23:48:10

US3442068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:54

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered '59'	System	21 Aug 2020 23:48:21

US3442068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:54

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:27:50
User entered 'Male (M)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:10

US3442068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:54

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:29:41
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:10

US3442068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:54

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:29:45
User entered 'l'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:10

US3442068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:54

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:25
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:10

US3442068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:54

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:25
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:10

US3442068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:54

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:25
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:10

US3442068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:54

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:25
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:10

US3442068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:25
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:10

US3442068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:54

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:25
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:10

US3442068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:54

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:25
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:10

US3442068

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:54

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:30:25
User entered '0'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:10

US3442068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:54

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:37:02
User entered '21 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:21

US3442068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'Aug 2020'	System	21 Aug 2020 23:48:21

US3442068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered '2020'	System	21 Aug 2020 23:48:21

US3442068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:54

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:37:05
User entered 'Amendment 2 (2)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:21

US3442068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:37:15
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:21

US3442068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:54

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:37:25
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:21

US3442068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:54

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:37:25
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:21

US3442068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:54

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:37:25
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:21

US3442068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:54

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:37:25
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 21:24:22

US3442068

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:54

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'I'	System	21 Aug 2020 23:48:27

US3442068

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:41:25
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:27

US3442068

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:40:54

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
Query 'two degenerative cervical discs diagnosis start date un/unk/2004 to 30dec2020. Please add this to logline' canceled (Site from CRA).		07 Apr 2021 13:49:47
User opened query 'two degenerative cervical discs diagnosis start date un/unk/2004 to 30dec2020. Please add this to logline' (Site from CRA).		06 Apr 2021 17:38:29
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:47:25
User entered 'Yes (Y)'		26 Aug 2020 23:37:19

US3442068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:48:08
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: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:37
Data point term sent to Coder	System	26 Aug 2020 23:38:49
User entered 'acid reflux'	(b) (4), (b) (6)	26 Aug 2020 23:37:53

US3442068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:48:10
User entered 'un UNK 2019'		26 Aug 2020 23:37:53

US3442068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:48:20
User entered '0'		26 Aug 2020 23:37:53

US3442068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:04:49
User closed query 'Source doesn't match. It does not reflect if the condition is on-going. Please update accordingly. ' (Site from CRA).		10 Nov 2020 23:04:08
Query 'Source doesn't match. It does not reflect if the condition is on-going. Please update accordingly. ' answered with 'source updated ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 14:28:56
User opened query 'Source doesn't match. It does not reflect if the condition is on-going. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 17:54:22
Query 'Source does not state the condition. Please update accordingly. ' canceled (Site from CRA).		17 Sep 2020 17:53:00
User opened query 'Source does not state the condition. Please update accordingly. ' (Site from CRA).		17 Sep 2020 17:50:58
Query 'Source doesn't match. Please update accordingly. ' canceled (Site from CRA).		17 Sep 2020 17:50:19
User opened query 'Source doesn't match. Please update accordingly. ' (Site from CRA).		17 Sep 2020 17:49:41
User entered 'Yes (Y)'		26 Aug 2020 23:37:53

US3442068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:04:51
User entered empty.		26 Aug 2020 23:37:53

US3442068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:04:52
User entered '0'		26 Aug 2020 23:37:53

US3442068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'Jan 2019'	System	26 Aug 2020 23:37:53

US3442068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered '2019'	System	26 Aug 2020 23:37:53

US3442068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	26 Aug 2020 23:37:53

US3442068

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	26 Aug 2020 23:37:53

US3442068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:55:59
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:38
Data point term sent to Coder	System	26 Aug 2020 23:39:50
User entered 'type 2 diabetes'	(b) (4), (b) (6)	26 Aug 2020 23:38:56

US3442068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:56:02
User entered 'un UNK 2015'		26 Aug 2020 23:38:56

US3442068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:56:04
User entered '0'		26 Aug 2020 23:38:56

US3442068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:56:11
User entered 'Yes (Y)'		26 Aug 2020 23:38:56

US3442068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:56:50
User entered empty.		26 Aug 2020 23:38:56

US3442068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:57:10
User entered '0'		26 Aug 2020 23:38:56

US3442068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'Jan 2015'	System	26 Aug 2020 23:38:56

US3442068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered '2015'	System	26 Aug 2020 23:38:56

US3442068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	26 Aug 2020 23:38:56

US3442068

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	26 Aug 2020 23:38:56

US3442068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:02:55
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:38
Data point term sent to Coder	System	26 Aug 2020 23:39:51
User entered 'hypertension'	(b) (4), (b) (6)	26 Aug 2020 23:39:14

US3442068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	17 Sep 2020 18:02:56
User entered 'un UNK 2012'		26 Aug 2020 23:39:14

US3442068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:02:58
User entered '0'		26 Aug 2020 23:39:14

US3442068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:03:00
User entered 'Yes (Y)'		26 Aug 2020 23:39:14

US3442068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:03:02
User entered empty.		26 Aug 2020 23:39:14

US3442068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:03:03
User entered '0'		26 Aug 2020 23:39:14

US3442068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'Jan 2012'	System	26 Aug 2020 23:39:14

US3442068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered '2012'	System	26 Aug 2020 23:39:14

US3442068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	26 Aug 2020 23:39:14

US3442068

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	26 Aug 2020 23:39:14

US3442068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:03:17
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:38
Data point term sent to Coder	System	26 Aug 2020 23:39:51
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	26 Aug 2020 23:39:50

US3442068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:03:18
User entered 'un UNK 2012'		26 Aug 2020 23:39:50

US3442068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:03:20
User entered '0'		26 Aug 2020 23:39:50

US3442068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:03:22
User entered 'Yes (Y)'		26 Aug 2020 23:39:50

US3442068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:03:24
User entered empty.		26 Aug 2020 23:39:50

US3442068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:03:25
User entered '0'		26 Aug 2020 23:39:50

US3442068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'Jan 2012'	System	26 Aug 2020 23:39:50

US3442068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered '2012'	System	26 Aug 2020 23:39:50

US3442068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	26 Aug 2020 23:39:50

US3442068

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	26 Aug 2020 23:39:50

US3442068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:04:21
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:39
Data point term sent to Coder	System	26 Aug 2020 23:40:52
User entered 'mild depression'	(b) (4), (b) (6)	26 Aug 2020 23:40:18

US3442068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:04:23
User entered 'un UNK 2019'		26 Aug 2020 23:40:18

US3442068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:04:24
User entered '0'		26 Aug 2020 23:40:18

US3442068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:04:26
User entered 'Yes (Y)'		26 Aug 2020 23:40:18

US3442068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:04:27
User entered empty.		26 Aug 2020 23:40:18

US3442068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:04:29
User entered '0'		26 Aug 2020 23:40:18

US3442068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'Jan 2019'	System	26 Aug 2020 23:40:18

US3442068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered '2019'	System	26 Aug 2020 23:40:18

US3442068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	26 Aug 2020 23:40:18

US3442068

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	26 Aug 2020 23:40:18

US3442068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:04:55
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:39
Data point term sent to Coder	System	26 Aug 2020 23:40:53
User entered 'anxiety'	(b) (4), (b) (6)	26 Aug 2020 23:40:38

US3442068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:04:57
User entered 'un UNK 2019'		26 Aug 2020 23:40:38

US3442068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:05:00
User entered '0'		26 Aug 2020 23:40:38

US3442068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:05:01
User entered 'Yes (Y)'		26 Aug 2020 23:40:38

US3442068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:05:08
User entered empty.		26 Aug 2020 23:40:38

US3442068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:05:09
User entered '0'		26 Aug 2020 23:40:38

US3442068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'Jan 2019'	System	26 Aug 2020 23:40:38

US3442068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered '2019'	System	26 Aug 2020 23:40:38

US3442068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	26 Aug 2020 23:40:38

US3442068

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	26 Aug 2020 23:40:38

US3442068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:05:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:37:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:37:58
Data point term sent to Coder	System	26 Aug 2020 23:41:53
User entered 'osteoathritis (bilateral knees and shoulders, neck)'	(b) (4), (b) (6)	26 Aug 2020 23:41:15

US3442068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:05:47
User entered 'un UNK 2010'		26 Aug 2020 23:41:15

US3442068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:05:51
User entered '0'		26 Aug 2020 23:41:15

US3442068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:05:52
User entered 'Yes (Y)'		26 Aug 2020 23:41:15

US3442068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:05:54
User entered empty.		26 Aug 2020 23:41:15

US3442068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:05:55
User entered '0'		26 Aug 2020 23:41:15

US3442068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'Jan 2010'	System	26 Aug 2020 23:41:15

US3442068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered '2010'	System	26 Aug 2020 23:41:15

US3442068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	26 Aug 2020 23:41:15

US3442068

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	26 Aug 2020 23:41:15

US3442068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:06:16
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:39
Data point term sent to Coder	System	26 Aug 2020 23:41:53
User entered 'migraines'	(b) (4), (b) (6)	26 Aug 2020 23:41:33

US3442068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:06:18
User entered 'un UNK 2019'		26 Aug 2020 23:41:33

US3442068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:06:19
User entered '0'		26 Aug 2020 23:41:33

US3442068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:06:22
User entered 'Yes (Y)'		26 Aug 2020 23:41:33

US3442068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:06:23
User entered empty.		26 Aug 2020 23:41:33

US3442068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:06:26
User entered '0'		26 Aug 2020 23:41:33

US3442068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'Jan 2019'	System	26 Aug 2020 23:41:33

US3442068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered '2019'	System	26 Aug 2020 23:41:33

US3442068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	26 Aug 2020 23:41:33

US3442068

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	26 Aug 2020 23:41:33

US3442068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:06:54
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy peripheral - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:38:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:38:22
Data point term sent to Coder	System	26 Aug 2020 23:42:54
User entered 'neuropathy in the left arm'	(b) (4), (b) (6)	26 Aug 2020 23:41:59

US3442068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:06:55
User entered 'un UNK 2009'		26 Aug 2020 23:41:59

US3442068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:06:57
User entered '0'		26 Aug 2020 23:41:59

US3442068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:07:03
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 13:56:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 13:56:49
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	27 Aug 2020 13:56:49
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 23:41:59
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 23:41:59

US3442068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:07:05
User entered empty.		26 Aug 2020 23:41:59

US3442068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:07:06
User entered '0'		26 Aug 2020 23:41:59

US3442068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'Jan 2009'	System	26 Aug 2020 23:41:59

US3442068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered '2009'	System	26 Aug 2020 23:41:59

US3442068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	26 Aug 2020 23:41:59

US3442068

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	26 Aug 2020 23:41:59

US3442068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:49:41
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Cervical disc degeneration - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:30:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:30:18
Data point term sent to Coder	System	06 Apr 2021 20:47:53
User entered 'two degenerative cervical discs'	Alma Guel (b) (4)	06 Apr 2021 20:47:29

US3442068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:49:40
User entered 'un UNK 2004'	Alma Guel (b) (4)	06 Apr 2021 20:47:29

US3442068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:49:38
User entered '0'	Alma Guel (b) (4)	06 Apr 2021 20:47:29

US3442068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:49:36
User entered 'No (N)' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:47:43
User entered 'Yes (Y)'	Alma Guel (b) (4)	06 Apr 2021 20:47:29

US3442068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:49:35
User entered '30 Dec 2020' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:47:43
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:47:29

US3442068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:49:33
User entered '0'	Alma Guel (b) (4)	06 Apr 2021 20:47:29

US3442068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:54

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'Jan 2004'	System	06 Apr 2021 20:47:29

US3442068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered '2004'	System	06 Apr 2021 20:47:29

US3442068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'Dec 2020'	System	06 Apr 2021 20:47:43
User entered empty.	System	06 Apr 2021 20:47:29

US3442068

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered '2020'	System	06 Apr 2021 20:47:43
User entered empty.	System	06 Apr 2021 20:47:29

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:11:10
User entered 'Yes (Y)'		26 Aug 2020 23:35:55

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:11:26
User entered '21 Aug 2020'		26 Aug 2020 23:35:55

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:11:32
User entered '16:48'		26 Aug 2020 23:35:55

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered '21 Aug 2020 16:48'	System	26 Aug 2020 23:35:55

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:11:48
User entered '66' in		26 Aug 2020 23:35:55
DataPoint set to visible.	System	21 Aug 2020 23:48:27

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:11:58
User entered '166.2' lb		26 Aug 2020 23:35:55
DataPoint set to visible.	System	21 Aug 2020 23:48:27

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
Amendment Manager: User entered '26.88147'	System	17 Sep 2020 00:19:30
User entered '26.9'	System	26 Aug 2020 23:35:55
DataPoint set to visible.	System	21 Aug 2020 23:48:27

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'kg/m2'	System	26 Aug 2020 23:35:55
DataPoint set to visible.	System	21 Aug 2020 23:48:27

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:12:15
User entered missing code ND - Not Done.		26 Aug 2020 23:35:55

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:12:15
User entered empty.		26 Aug 2020 23:35:55

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:12:15
User entered empty.		26 Aug 2020 23:35:55

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:12:15
User entered missing code ND - Not Done.		26 Aug 2020 23:35:55

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'bpm'	System	26 Aug 2020 23:35:55

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:12:15
User entered missing code ND - Not Done.		26 Aug 2020 23:35:55

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'breaths/min'	System	26 Aug 2020 23:35:55

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:12:15
User entered missing code ND - Not Done.		26 Aug 2020 23:35:55

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'mmHg'	System	26 Aug 2020 23:35:55

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:12:15
User entered missing code ND - Not Done.		26 Aug 2020 23:35:55

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'mmHg'	System	26 Aug 2020 23:35:55

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46

US3442068

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46

US3442068

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:14:32
User entered 'Yes (Y)'		26 Aug 2020 23:42:27

US3442068

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:14:37
User entered '21 Aug 2020'		26 Aug 2020 23:42:27

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

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 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered 'No (N)'		26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

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 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered 'No (N)'		26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

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 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered 'No (N)'		26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

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 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered 'No (N)'		26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

[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 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered 'No (N)'		26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

[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 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered 'No (N)'		26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

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 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered 'No (N)'		26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

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 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered 'No (N)'		26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

[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 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered 'No (N)'		26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

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 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered 'No (N)'		26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

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 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered 'No (N)'		26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered 'Yes (Y)'		26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	17 Sep 2020 18:16:17
User entered 'government position'		26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered '0'		26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

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 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered '0'		26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

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 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered '0'		26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

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 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered '0'		26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered 'I'		26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 23:34:13

US3442068

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered empty.		26 Aug 2020 23:34:13

US3442068

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:21:56
User entered 'Yes (Y)'		21 Aug 2020 23:48:40

US3442068

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:21:58
User entered '21 Aug 2020'		21 Aug 2020 23:48:40

US3442068

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:17:56
User closed query 'Source does not reflect this visit type as clinic visit. Please update the source and make the changes in this field accordingly. ' (Site from CRA).		10 Dec 2020 20:17:54
Query 'Source does not reflect this visit type as clinic visit. Please update the source and make the changes in this field accordingly. ' answered with 'updated in source' (Site from CRA).	Alma Guel (b) (4)	10 Dec 2020 20:17:48
User opened query 'Source does not reflect this visit type as clinic visit. Please update the source and make the changes in this field accordingly. ' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 18:08:10
User entered 'Clinic (Clinic)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:48:40

US3442068

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'VISIT1'	System	21 Aug 2020 23:48:40

US3442068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:28:59
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 23:09:12

US3442068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:54

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:18:37
User entered '144628'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 23:09:12

US3442068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:54

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:18:18
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 23:09:12

US3442068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:54

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)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:18:20
User entered 'No (N)'		26 Aug 2020 23:35:05

US3442068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:54

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)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:18:22
User entered 'No (N)'		26 Aug 2020 23:35:05

US3442068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:54

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:18:23
User entered 'No (N)'		26 Aug 2020 23:35:05

US3442068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:54

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:18:25
User entered 'Yes (Y)'		26 Aug 2020 23:35:05

US3442068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:54

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:18:26
User entered 'No (N)'		26 Aug 2020 23:35:05

US3442068

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:54

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:08:22
User entered 'No (N)'		22 Sep 2020 22:10:31
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:38:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:14:25

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:39
User entered missing code ND - Not Done.		26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:41
User entered missing code ND - Not Done.		26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:39
User entered missing code ND - Not Done.		26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:54

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:41
User entered missing code ND - Not Done.		26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User accepted default value 'Pre-Dose (PREDOSE)'		26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:32
User entered 'Yes (Y)'		26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:34
User entered '21 Aug 2020'		26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:36
User entered '16:48'		26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered '21 Aug 2020 16:48'	System	26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:41
User entered '96.9' F		26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:51
User entered 'Oral (Oral)'		26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:32:55
User entered empty.		26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:33:03
User entered '54'		26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'bpm'	System	26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:02:42
User entered '13'		26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'breaths/min'	System	26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:03:03
User entered '154'		26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'mmHg'	System	26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:03:06
User entered '71'		26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'mmHg'	System	26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:39
User entered missing code ND - Not Done.		26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:54

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:31:41
User entered missing code ND - Not Done.		26 Aug 2020 23:36:45

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User accepted default value 'Post-Dose (POSTDOSE)'		26 Aug 2020 23:44:09

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:05:23
User entered 'Yes (Y)'		26 Aug 2020 23:44:09

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:05:24
User entered '21 Aug 2020'		26 Aug 2020 23:44:09

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:05:32
User entered '19:10'		26 Aug 2020 23:44:09

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered '21 Aug 2020 19:10'	System	26 Aug 2020 23:44:09

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User closed query 'Per CDM, Response noted; However please advice if the out of range value is CS/NCS. If CS, please report as AE as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 10:03:05
Query 'Per CDM, Response noted; However please advice if the out of range value is CS/NCS. If CS, please report as AE as appropriate.' answered with 'Temp is correct as entered. It was rechecked and remained the same. It is not clinically significant.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 19:49:46
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 12:54:19
User opened query 'Per CDM, Response noted; However please advice if the out of range value is CS/NCS. If CS, please report as AE as appropriate.' (Site from DM).		21 Sep 2020 12:54:16
DataPoint Verified.		17 Sep 2020 19:11:06
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'temp is correct as entered. temp was rechecked and remained the same.' (Site from System).		17 Sep 2020 17:44:38
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:19:30
User entered '96.6' F	(b) (4), (b) (6)	26 Aug 2020 23:44:09

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:17:08
User entered 'Oral (Oral)'		26 Aug 2020 23:44:09

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:17:11
User entered empty.		26 Aug 2020 23:44:09

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:17:15
User entered '55'		26 Aug 2020 23:44:09

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'bpm'	System	26 Aug 2020 23:44:09

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:17:17
User entered '13'		26 Aug 2020 23:44:09

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'breaths/min'	System	26 Aug 2020 23:44:09

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:29:32
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		27 Aug 2020 13:16:03
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'correct as entered. NCS per investigator' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 23:44:14
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	26 Aug 2020 23:44:09
User entered '157'	(b) (4), (b) (6)	26 Aug 2020 23:44:09

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'mmHg'	System	26 Aug 2020 23:44:09

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:18:19
User entered '86'		26 Aug 2020 23:44:09

US3442068

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'mmHg'	System	26 Aug 2020 23:44:09

US3442068

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:26:59
User entered 'No (N)'		26 Aug 2020 23:34:32

US3442068

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:27:01
User entered empty.		26 Aug 2020 23:34:32

US3442068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:27:09
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:49:13

US3442068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:28:40
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:49:13

US3442068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

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 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:30:58
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:49:13

US3442068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 23:49:13

US3442068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:28:45
User entered '21 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:49:13

US3442068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:28:53
User entered '18:37'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:49:13

US3442068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered '21 Aug 2020 18:37'	System	21 Aug 2020 23:49:13

US3442068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:29:09
User entered 'Left Arm (LEFT ARM)'	Melody Dufrene (b) (4) (b) (4)	21 Aug 2020 23:49:13

US3442068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
DataPoint Verified.		17 Sep 2020 19:29:15
User entered 'ONCE'	System	21 Aug 2020 23:49:13

US3442068

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 23:49:13

US3442068

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:31:37
User entered 'Yes (Y)'		26 Aug 2020 23:42:53

US3442068

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:31:48
User entered '21 Aug 2020'		26 Aug 2020 23:42:53

US3442068

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:31:52
User entered '17:49'		26 Aug 2020 23:42:53

US3442068

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered '21 Aug 2020 17:49'	System	26 Aug 2020 23:42:53

US3442068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:40:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:31:58
User entered '21 Aug 2020'		26 Aug 2020 23:43:13

US3442068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		26 Aug 2020 23:43:13

US3442068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:32:07
User entered 'Yes (Y)'		26 Aug 2020 23:43:13

US3442068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:32:11
User entered '17:45'		26 Aug 2020 23:43:13

US3442068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered '21 Aug 2020 17:45'	System	26 Aug 2020 23:43:13

US3442068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		26 Aug 2020 23:43:13

US3442068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:38:03
User entered 'No (N)'		26 Aug 2020 23:43:13

US3442068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 21:38:04
User entered empty.		26 Aug 2020 23:43:13

US3442068

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered empty.	System	26 Aug 2020 23:43:13

US3442068

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:33:20
User entered 'Yes (Y)'		26 Aug 2020 23:43:19

US3442068

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'I'	System	26 Aug 2020 23:43:19

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-21T19:06:35', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '4359c321-7572-41a2-b010-9f97d9797494'	System	22 Aug 2020 00:07:04
User entered 'Yes (Y)'	System	22 Aug 2020 00:07:04

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-21T19:06:41', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '4359c321-7572-41a2-b010-9f97d9797494'	System	22 Aug 2020 00:07:04
User entered '96.6'	System	22 Aug 2020 00:07:04

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-21T19:06:49', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '4359c321-7572-41a2-b010-9f97d9797494'	System	22 Aug 2020 00:07:04
User entered 'No (N)'	System	22 Aug 2020 00:07:04

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-21T19:07:00', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '4359c321-7572-41a2-b010-9f97d9797494'	System	22 Aug 2020 00:07:04
User entered '21 Aug 2020 19:07'	System	22 Aug 2020 00:07:04

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '21 Aug 2020 18:57'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '21 Aug 2020 21:27'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-22T11:51:43', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'b1ed4feb-dfa0-4d62-afa2-d9debc941938'	System	22 Aug 2020 16:52:10
User entered 'Yes (Y)'	System	22 Aug 2020 16:52:10

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-22T11:51:50', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'b1ed4feb-dfa0-4d62-afa2-d9debc941938'	System	22 Aug 2020 16:52:10
User entered '97.2'	System	22 Aug 2020 16:52:10

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-22T11:51:55', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'b1ed4feb-dfa0-4d62-afa2-d9debc941938'	System	22 Aug 2020 16:52:10
User entered 'No (N)'	System	22 Aug 2020 16:52:10

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-22T11:52:06', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'b1ed4feb-dfa0-4d62-afa2-d9debc941938'	System	22 Aug 2020 16:52:10
User entered '22 Aug 2020 11:52'	System	22 Aug 2020 16:52:10

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '21 Aug 2020 22:22'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 2'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-23T11:24:27', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '9f183140-96c8-4272-98c5-6c66fd01ad30'	System	23 Aug 2020 16:24:49
User entered 'Yes (Y)'	System	23 Aug 2020 16:24:49

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-23T11:24:34', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '9f183140-96c8-4272-98c5-6c66fd01ad30'	System	23 Aug 2020 16:24:49
User entered '96.7'	System	23 Aug 2020 16:24:49

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-23T11:24:39', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '9f183140-96c8-4272-98c5-6c66fd01ad30'	System	23 Aug 2020 16:24:49
User entered 'No (N)'	System	23 Aug 2020 16:24:49

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-23T11:24:43', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '9f183140-96c8-4272-98c5-6c66fd01ad30'	System	23 Aug 2020 16:24:49
User entered '23 Aug 2020 11:24'	System	23 Aug 2020 16:24:49

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 3'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-24T11:24:03', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '08df9b2a-4bc7-4aed-b7b4-9654ba25588e'	System	24 Aug 2020 16:24:26
User entered 'Yes (Y)'	System	24 Aug 2020 16:24:26

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-24T11:24:14', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '08df9b2a-4bc7-4aed-b7b4-9654ba25588e'	System	24 Aug 2020 16:24:26
User entered '96.7'	System	24 Aug 2020 16:24:26

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-24T11:24:19', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '08df9b2a-4bc7-4aed-b7b4-9654ba25588e'	System	24 Aug 2020 16:24:26
User entered 'No (N)'	System	24 Aug 2020 16:24:26

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-24T11:24:23', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '08df9b2a-4bc7-4aed-b7b4-9654ba25588e'	System	24 Aug 2020 16:24:26
User entered '24 Aug 2020 11:24'	System	24 Aug 2020 16:24:26

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 4'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-25T07:43:48', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '5e3fa609-7ccd-45a6-945c-48037bd966a9'	System	25 Aug 2020 12:44:14
User entered 'Yes (Y)'	System	25 Aug 2020 12:44:14

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-25T07:44:00', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '5e3fa609-7ccd-45a6-945c-48037bd966a9'	System	25 Aug 2020 12:44:14
User entered '97.4'	System	25 Aug 2020 12:44:14

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-25T07:44:07', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '5e3fa609-7ccd-45a6-945c-48037bd966a9'	System	25 Aug 2020 12:44:14
User entered 'No (N)'	System	25 Aug 2020 12:44:14

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-25T07:44:11', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '5e3fa609-7ccd-45a6-945c-48037bd966a9'	System	25 Aug 2020 12:44:14
User entered '25 Aug 2020 07:44'	System	25 Aug 2020 12:44:14

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 5'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-26T09:06:03', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'fe1aa30d-d0e7-44ba-b66a-a4f4b14ce461'	System	26 Aug 2020 14:06:27
User entered 'Yes (Y)'	System	26 Aug 2020 14:06:27

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-26T09:06:09', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'fe1aa30d-d0e7-44ba-b66a-a4f4b14ce461'	System	26 Aug 2020 14:06:27
User entered '96.8'	System	26 Aug 2020 14:06:27

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-26T09:06:20', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'fe1aa30d-d0e7-44ba-b66a-a4f4b14ce461'	System	26 Aug 2020 14:06:27
User entered 'No (N)'	System	26 Aug 2020 14:06:27

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-26T09:06:24', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'fe1aa30d-d0e7-44ba-b66a-a4f4b14ce461'	System	26 Aug 2020 14:06:27
User entered '26 Aug 2020 09:06'	System	26 Aug 2020 14:06:27

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 6'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-27T09:34:18', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '7eefd331-5cdd-439d-8760-9310c3f33c26'	System	27 Aug 2020 14:34:36
User entered 'Yes (Y)'	System	27 Aug 2020 14:34:36

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-27T09:34:24', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '7eefd331-5cdd-439d-8760-9310c3f33c26'	System	27 Aug 2020 14:34:36
User entered '96.6'	System	27 Aug 2020 14:34:36

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-27T09:34:28', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '7eefd331-5cdd-439d-8760-9310c3f33c26'	System	27 Aug 2020 14:34:36
User entered 'No (N)'	System	27 Aug 2020 14:34:36

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-27T09:34:33', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '7eefd331-5cdd-439d-8760-9310c3f33c26'	System	27 Aug 2020 14:34:36
User entered '27 Aug 2020 09:34'	System	27 Aug 2020 14:34:36

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 7'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-28T09:31:04', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'dd8c33a1-1246-4199-aea7-d5e2e440ed12'	System	28 Aug 2020 14:31:12
User entered 'Yes (Y)'	System	28 Aug 2020 14:31:12

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-28T09:30:50', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'dd8c33a1-1246-4199-aea7-d5e2e440ed12'	System	28 Aug 2020 14:31:12
User entered '96.8'	System	28 Aug 2020 14:31:12

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-28T09:30:57', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'dd8c33a1-1246-4199-aea7-d5e2e440ed12'	System	28 Aug 2020 14:31:12
User entered 'No (N)'	System	28 Aug 2020 14:31:12

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-28T09:31:08', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'dd8c33a1-1246-4199-aea7-d5e2e440ed12'	System	28 Aug 2020 14:31:12
User entered '28 Aug 2020 09:31'	System	28 Aug 2020 14:31:12

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-21T19:07:13', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '4d3499e4-c3b7-4c2d-a787-9d01c54487b3'	System	22 Aug 2020 00:07:28
User entered 'None (1)'	System	22 Aug 2020 00:07:28

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-21T19:07:16', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '4d3499e4-c3b7-4c2d-a787-9d01c54487b3'	System	22 Aug 2020 00:07:28
User entered 'No (N)'	System	22 Aug 2020 00:07:28

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-21T19:07:19', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '4d3499e4-c3b7-4c2d-a787-9d01c54487b3'	System	22 Aug 2020 00:07:28
User entered 'No (N)'	System	22 Aug 2020 00:07:28

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-21T19:07:23', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '4d3499e4-c3b7-4c2d-a787-9d01c54487b3'	System	22 Aug 2020 00:07:28
User entered 'None (1)'	System	22 Aug 2020 00:07:28

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-21T19:07:25', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '4d3499e4-c3b7-4c2d-a787-9d01c54487b3'	System	22 Aug 2020 00:07:28
User entered '21 Aug 2020 19:07'	System	22 Aug 2020 00:07:28

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '21 Aug 2020 18:57'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '21 Aug 2020 21:27'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-22T11:52:22', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'a44cc2a3-fdb6-42d7-9b8d-8b9f3be66aac'	System	22 Aug 2020 16:54:09
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 16:54:09

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-22T11:52:38', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'a44cc2a3-fdb6-42d7-9b8d-8b9f3be66aac'	System	22 Aug 2020 16:54:09
User entered 'No (N)'	System	22 Aug 2020 16:54:09

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-22T11:53:04', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'a44cc2a3-fdb6-42d7-9b8d-8b9f3be66aac'	System	22 Aug 2020 16:54:09
User entered 'Yes (Y)'	System	22 Aug 2020 16:54:09

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-22T11:53:55', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'a44cc2a3-fdb6-42d7-9b8d-8b9f3be66aac'	System	22 Aug 2020 16:54:09
User entered '5'	System	22 Aug 2020 16:54:09

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-22T11:54:03', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'a44cc2a3-fdb6-42d7-9b8d-8b9f3be66aac'	System	22 Aug 2020 16:54:09
User entered 'None (1)'	System	22 Aug 2020 16:54:09

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-22T11:54:06', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'a44cc2a3-fdb6-42d7-9b8d-8b9f3be66aac'	System	22 Aug 2020 16:54:09
User entered '22 Aug 2020 11:54'	System	22 Aug 2020 16:54:09

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '21 Aug 2020 22:22'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 2'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-23T11:24:55', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '0b42e4da-10e6-4348-a1dd-44e4c5d2dec0'	System	23 Aug 2020 16:25:35
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 16:25:35

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-23T11:24:59', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '0b42e4da-10e6-4348-a1dd-44e4c5d2dec0'	System	23 Aug 2020 16:25:35
User entered 'No (N)'	System	23 Aug 2020 16:25:35

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-23T11:25:08', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '0b42e4da-10e6-4348-a1dd-44e4c5d2dec0'	System	23 Aug 2020 16:25:35
User entered 'Yes (Y)'	System	23 Aug 2020 16:25:35

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

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)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-23T11:25:14', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '0b42e4da-10e6-4348-a1dd-44e4c5d2dec0'	System	23 Aug 2020 16:25:35
User entered '3'	System	23 Aug 2020 16:25:35

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-23T11:25:18', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '0b42e4da-10e6-4348-a1dd-44e4c5d2dec0'	System	23 Aug 2020 16:25:35
User entered 'None (1)'	System	23 Aug 2020 16:25:35

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-23T11:25:21', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '0b42e4da-10e6-4348-a1dd-44e4c5d2dec0'	System	23 Aug 2020 16:25:35
User entered '23 Aug 2020 11:25'	System	23 Aug 2020 16:25:35

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 3'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-24T11:24:31', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '071a2833-b408-4083-bc73-34a9de02c4db'	System	24 Aug 2020 16:25:29
User entered 'Does not interfere with activity (2)'	System	24 Aug 2020 16:25:29

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-24T11:24:35', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '071a2833-b408-4083-bc73-34a9de02c4db'	System	24 Aug 2020 16:25:29
User entered 'No (N)'	System	24 Aug 2020 16:25:29

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-24T11:24:39', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '071a2833-b408-4083-bc73-34a9de02c4db'	System	24 Aug 2020 16:25:29
User entered 'Yes (Y)'	System	24 Aug 2020 16:25:29

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

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)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-24T11:25:15', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '071a2833-b408-4083-bc73-34a9de02c4db'	System	24 Aug 2020 16:25:29
User entered '2'	System	24 Aug 2020 16:25:29

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-24T11:25:22', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '071a2833-b408-4083-bc73-34a9de02c4db'	System	24 Aug 2020 16:25:29
User entered 'None (1)'	System	24 Aug 2020 16:25:29

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-24T11:25:26', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '071a2833-b408-4083-bc73-34a9de02c4db'	System	24 Aug 2020 16:25:29
User entered '24 Aug 2020 11:25'	System	24 Aug 2020 16:25:29

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 4'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-25T07:44:33', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '634de90c-5566-4bc4-826c-de5b8c4f3067'	System	25 Aug 2020 12:45:17
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 12:45:17

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-25T07:44:41', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '634de90c-5566-4bc4-826c-de5b8c4f3067'	System	25 Aug 2020 12:45:17
User entered 'No (N)'	System	25 Aug 2020 12:45:17

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-25T07:44:57', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '634de90c-5566-4bc4-826c-de5b8c4f3067'	System	25 Aug 2020 12:45:17
User entered 'Yes (Y)'	System	25 Aug 2020 12:45:17

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

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)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-25T07:45:02', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '634de90c-5566-4bc4-826c-de5b8c4f3067'	System	25 Aug 2020 12:45:17
User entered '1'	System	25 Aug 2020 12:45:17

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-25T07:45:09', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '634de90c-5566-4bc4-826c-de5b8c4f3067'	System	25 Aug 2020 12:45:17
User entered 'None (1)'	System	25 Aug 2020 12:45:17

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-25T07:45:14', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '634de90c-5566-4bc4-826c-de5b8c4f3067'	System	25 Aug 2020 12:45:17
User entered '25 Aug 2020 07:45'	System	25 Aug 2020 12:45:17

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 5'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-26T09:06:29', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '18a7c28b-767e-48ea-8ea4-3a9670a94eff'	System	26 Aug 2020 14:06:45
User entered 'None (1)'	System	26 Aug 2020 14:06:45

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-26T09:06:32', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '18a7c28b-767e-48ea-8ea4-3a9670a94eff'	System	26 Aug 2020 14:06:45
User entered 'No (N)'	System	26 Aug 2020 14:06:45

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-26T09:06:35', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '18a7c28b-767e-48ea-8ea4-3a9670a94eff'	System	26 Aug 2020 14:06:45
User entered 'No (N)'	System	26 Aug 2020 14:06:45

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-26T09:06:37', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '18a7c28b-767e-48ea-8ea4-3a9670a94eff'	System	26 Aug 2020 14:06:45
User entered 'None (1)'	System	26 Aug 2020 14:06:45

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-26T09:06:40', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '18a7c28b-767e-48ea-8ea4-3a9670a94eff'	System	26 Aug 2020 14:06:45
User entered '26 Aug 2020 09:06'	System	26 Aug 2020 14:06:45

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 6'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-27T09:34:45', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'fe583413-29a3-4de6-a4b0-f4954736969a'	System	27 Aug 2020 14:35:09
User entered 'None (1)'	System	27 Aug 2020 14:35:09

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-27T09:34:55', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'fe583413-29a3-4de6-a4b0-f4954736969a'	System	27 Aug 2020 14:35:09
User entered 'No (N)'	System	27 Aug 2020 14:35:09

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-27T09:35:00', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'fe583413-29a3-4de6-a4b0-f4954736969a'	System	27 Aug 2020 14:35:09
User entered 'No (N)'	System	27 Aug 2020 14:35:09

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-27T09:35:02', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'fe583413-29a3-4de6-a4b0-f4954736969a'	System	27 Aug 2020 14:35:09
User entered 'None (1)'	System	27 Aug 2020 14:35:09

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-27T09:35:05', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'fe583413-29a3-4de6-a4b0-f4954736969a'	System	27 Aug 2020 14:35:09
User entered '27 Aug 2020 09:35'	System	27 Aug 2020 14:35:09

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 7'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-28T09:31:12', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '06e4e0ca-9716-4e7a-9a37-525d93fdd7fa'	System	28 Aug 2020 14:31:27
User entered 'None (1)'	System	28 Aug 2020 14:31:27

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-28T09:31:15', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '06e4e0ca-9716-4e7a-9a37-525d93fdd7fa'	System	28 Aug 2020 14:31:27
User entered 'No (N)'	System	28 Aug 2020 14:31:27

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-28T09:31:17', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '06e4e0ca-9716-4e7a-9a37-525d93fdd7fa'	System	28 Aug 2020 14:31:27
User entered 'No (N)'	System	28 Aug 2020 14:31:27

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-28T09:31:19', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '06e4e0ca-9716-4e7a-9a37-525d93fdd7fa'	System	28 Aug 2020 14:31:27
User entered 'None (1)'	System	28 Aug 2020 14:31:27

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-28T09:31:22', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '06e4e0ca-9716-4e7a-9a37-525d93fdd7fa'	System	28 Aug 2020 14:31:27
User entered '28 Aug 2020 09:31'	System	28 Aug 2020 14:31:27

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-21T19:07:31', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '942015b7-f33f-48dc-b71e-1cdbdd9464d8'	System	22 Aug 2020 00:08:30
User entered 'None (0)'	System	22 Aug 2020 00:08:30

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-21T19:07:35', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '942015b7-f33f-48dc-b71e-1cdbdd9464d8'	System	22 Aug 2020 00:08:30
User entered 'None (0)'	System	22 Aug 2020 00:08:30

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-21T19:07:56', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '942015b7-f33f-48dc-b71e-1cdbdd9464d8'	System	22 Aug 2020 00:08:30
User entered 'None (0)'	System	22 Aug 2020 00:08:30

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-21T19:07:59', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '942015b7-f33f-48dc-b71e-1cdbdd9464d8'	System	22 Aug 2020 00:08:30
User entered 'None (0)'	System	22 Aug 2020 00:08:30

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-21T19:08:02', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '942015b7-f33f-48dc-b71e-1cdbdd9464d8'	System	22 Aug 2020 00:08:30
User entered 'None (0)'	System	22 Aug 2020 00:08:30

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-21T19:08:08', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '942015b7-f33f-48dc-b71e-1cdbdd9464d8'	System	22 Aug 2020 00:08:30
User entered 'None (0)'	System	22 Aug 2020 00:08:30

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-21T19:08:24', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '942015b7-f33f-48dc-b71e-1cdbdd9464d8'	System	22 Aug 2020 00:08:30
User entered 'No (N)'	System	22 Aug 2020 00:08:30

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-21T19:08:27', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '942015b7-f33f-48dc-b71e-1cdbdd9464d8'	System	22 Aug 2020 00:08:30
User entered '21 Aug 2020 19:08'	System	22 Aug 2020 00:08:30

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '21 Aug 2020 18:57'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '21 Aug 2020 21:27'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-22T11:54:15', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'f805401b-8c4d-4432-834c-232cdbc16639'	System	22 Aug 2020 16:54:55
User entered 'None (0)'	System	22 Aug 2020 16:54:55

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-22T11:54:18', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'f805401b-8c4d-4432-834c-232cdbc16639'	System	22 Aug 2020 16:54:55
User entered 'None (0)'	System	22 Aug 2020 16:54:55

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-22T11:54:29', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'f805401b-8c4d-4432-834c-232cddb16639'	System	22 Aug 2020 16:54:55
User entered 'None (0)'	System	22 Aug 2020 16:54:55

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-22T11:54:34', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'f805401b-8c4d-4432-834c-232cdbc16639'	System	22 Aug 2020 16:54:55
User entered 'None (0)'	System	22 Aug 2020 16:54:55

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-22T11:54:37', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'f805401b-8c4d-4432-834c-232cdbc16639'	System	22 Aug 2020 16:54:55
User entered 'None (0)'	System	22 Aug 2020 16:54:55

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-22T11:54:41', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'f805401b-8c4d-4432-834c-232cdbd16639'	System	22 Aug 2020 16:54:55
User entered 'None (0)'	System	22 Aug 2020 16:54:55

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-22T11:54:48', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'f805401b-8c4d-4432-834c-232cdbc16639'	System	22 Aug 2020 16:54:55
User entered 'No (N)'	System	22 Aug 2020 16:54:55

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-22T11:54:52', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'f805401b-8c4d-4432-834c-232cdbd16639'	System	22 Aug 2020 16:54:55
User entered '22 Aug 2020 11:54'	System	22 Aug 2020 16:54:55

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '21 Aug 2020 22:22'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 2'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-23T11:25:27', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'a0ca1f07-4924-4d0a-9fca-52f80b14c098'	System	23 Aug 2020 16:25:48
User entered 'None (0)'	System	23 Aug 2020 16:25:48

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-23T11:25:29', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'a0ca1f07-4924-4d0a-9fca-52f80b14c098'	System	23 Aug 2020 16:25:48
User entered 'None (0)'	System	23 Aug 2020 16:25:48

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-23T11:25:31', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'a0ca1f07-4924-4d0a-9fca-52f80b14c098'	System	23 Aug 2020 16:25:48
User entered 'None (0)'	System	23 Aug 2020 16:25:48

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-23T11:25:33', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'a0ca1f07-4924-4d0a-9fca-52f80b14c098'	System	23 Aug 2020 16:25:48
User entered 'None (0)'	System	23 Aug 2020 16:25:48

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-23T11:25:35', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'a0ca1f07-4924-4d0a-9fca-52f80b14c098'	System	23 Aug 2020 16:25:48
User entered 'None (0)'	System	23 Aug 2020 16:25:48

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-23T11:25:37', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'a0ca1f07-4924-4d0a-9fca-52f80b14c098'	System	23 Aug 2020 16:25:48
User entered 'None (0)'	System	23 Aug 2020 16:25:48

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-23T11:25:43', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'a0ca1f07-4924-4d0a-9fca-52f80b14c098'	System	23 Aug 2020 16:25:48
User entered 'No (N)'	System	23 Aug 2020 16:25:48

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-23T11:25:46', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'a0ca1f07-4924-4d0a-9fca-52f80b14c098'	System	23 Aug 2020 16:25:48
User entered '23 Aug 2020 11:25'	System	23 Aug 2020 16:25:48

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 3'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-24T11:25:30', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '48012fa0-4a0b-44ff-b287-954620f74f2c'	System	24 Aug 2020 16:25:59
User entered 'None (0)'	System	24 Aug 2020 16:25:59

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-24T11:25:33', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '48012fa0-4a0b-44ff-b287-954620f74f2c'	System	24 Aug 2020 16:25:59
User entered 'None (0)'	System	24 Aug 2020 16:25:59

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-24T11:25:36', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '48012fa0-4a0b-44ff-b287-954620f74f2c'	System	24 Aug 2020 16:25:59
User entered 'None (0)'	System	24 Aug 2020 16:25:59

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-24T11:25:43', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '48012fa0-4a0b-44ff-b287-954620f74f2c'	System	24 Aug 2020 16:25:59
User entered 'None (0)'	System	24 Aug 2020 16:25:59

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-24T11:25:45', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '48012fa0-4a0b-44ff-b287-954620f74f2c'	System	24 Aug 2020 16:25:59
User entered 'None (0)'	System	24 Aug 2020 16:25:59

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-24T11:25:48', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '48012fa0-4a0b-44ff-b287-954620f74f2c'	System	24 Aug 2020 16:25:59
User entered 'None (0)'	System	24 Aug 2020 16:25:59

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-24T11:25:54', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '48012fa0-4a0b-44ff-b287-954620f74f2c'	System	24 Aug 2020 16:25:59
User entered 'No (N)'	System	24 Aug 2020 16:25:59

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-24T11:25:57', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '48012fa0-4a0b-44ff-b287-954620f74f2c'	System	24 Aug 2020 16:25:59
User entered '24 Aug 2020 11:25'	System	24 Aug 2020 16:25:59

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 4'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-25T07:45:39', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '4d12fd2c-c56a-4d1c-8494-fdcaa56670e8'	System	25 Aug 2020 12:46:11
User entered 'None (0)'	System	25 Aug 2020 12:46:11

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-25T07:45:47', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '4d12fd2c-c56a-4d1c-8494-fdcaa56670e8'	System	25 Aug 2020 12:46:11
User entered 'None (0)'	System	25 Aug 2020 12:46:11

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-25T07:45:50', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '4d12fd2c-c56a-4d1c-8494-fdcaa56670e8'	System	25 Aug 2020 12:46:11
User entered 'None (0)'	System	25 Aug 2020 12:46:11

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-25T07:45:55', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '4d12fd2c-c56a-4d1c-8494-fdcaa56670e8'	System	25 Aug 2020 12:46:11
User entered 'None (0)'	System	25 Aug 2020 12:46:11

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-25T07:45:58', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '4d12fd2c-c56a-4d1c-8494-fdcaa56670e8'	System	25 Aug 2020 12:46:11
User entered 'None (0)'	System	25 Aug 2020 12:46:11

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-25T07:46:00', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '4d12fd2c-c56a-4d1c-8494-fdcaa56670e8'	System	25 Aug 2020 12:46:11
User entered 'None (0)'	System	25 Aug 2020 12:46:11

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-25T07:46:04', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '4d12fd2c-c56a-4d1c-8494-fdcaa56670e8'	System	25 Aug 2020 12:46:11
User entered 'No (N)'	System	25 Aug 2020 12:46:11

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-25T07:46:08', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '4d12fd2c-c56a-4d1c-8494-fdcaa56670e8'	System	25 Aug 2020 12:46:11
User entered '25 Aug 2020 07:46'	System	25 Aug 2020 12:46:11

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 5'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-26T09:06:45', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'f1a5ec3d-4937-4ec5-8ba2-caf9392683f8'	System	26 Aug 2020 14:07:04
User entered 'None (0)'	System	26 Aug 2020 14:07:04

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-26T09:06:47', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'f1a5ec3d-4937-4ec5-8ba2-caf9392683f8'	System	26 Aug 2020 14:07:04
User entered 'None (0)'	System	26 Aug 2020 14:07:04

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-26T09:06:48', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'f1a5ec3d-4937-4ec5-8ba2-caf9392683f8'	System	26 Aug 2020 14:07:04
User entered 'None (0)'	System	26 Aug 2020 14:07:04

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-26T09:06:50', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'f1a5ec3d-4937-4ec5-8ba2-caf9392683f8'	System	26 Aug 2020 14:07:04
User entered 'None (0)'	System	26 Aug 2020 14:07:04

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-26T09:06:52', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'f1a5ec3d-4937-4ec5-8ba2-caf9392683f8'	System	26 Aug 2020 14:07:04
User entered 'None (0)'	System	26 Aug 2020 14:07:04

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-26T09:06:53', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'f1a5ec3d-4937-4ec5-8ba2-caf9392683f8'	System	26 Aug 2020 14:07:04
User entered 'None (0)'	System	26 Aug 2020 14:07:04

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-26T09:06:56', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'f1a5ec3d-4937-4ec5-8ba2-caf9392683f8'	System	26 Aug 2020 14:07:04
User entered 'No (N)'	System	26 Aug 2020 14:07:04

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-26T09:06:59', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'f1a5ec3d-4937-4ec5-8ba2-caf9392683f8'	System	26 Aug 2020 14:07:04
User entered '26 Aug 2020 09:06'	System	26 Aug 2020 14:07:04

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 6'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-27T09:35:10', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ea82dfa9-f84f-4ab8-a73d-35d3367dbf9b'	System	27 Aug 2020 14:35:36
User entered 'None (0)'	System	27 Aug 2020 14:35:36

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-27T09:35:12', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ea82dfa9-f84f-4ab8-a73d-35d3367dbf9b'	System	27 Aug 2020 14:35:36
User entered 'None (0)'	System	27 Aug 2020 14:35:36

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-27T09:35:15', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ea82dfa9-f84f-4ab8-a73d-35d3367dbf9b'	System	27 Aug 2020 14:35:36
User entered 'None (0)'	System	27 Aug 2020 14:35:36

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-27T09:35:18', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ea82dfa9-f84f-4ab8-a73d-35d3367dbf9b'	System	27 Aug 2020 14:35:36
User entered 'None (0)'	System	27 Aug 2020 14:35:36

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-27T09:35:20', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ea82dfa9-f84f-4ab8-a73d-35d3367dbf9b'	System	27 Aug 2020 14:35:36
User entered 'None (0)'	System	27 Aug 2020 14:35:36

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-27T09:35:23', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ea82dfa9-f84f-4ab8-a73d-35d3367dbf9b'	System	27 Aug 2020 14:35:36
User entered 'None (0)'	System	27 Aug 2020 14:35:36

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-27T09:35:28', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ea82dfa9-f84f-4ab8-a73d-35d3367dbf9b'	System	27 Aug 2020 14:35:36
User entered 'No (N)'	System	27 Aug 2020 14:35:36

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-27T09:35:31', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ea82dfa9-f84f-4ab8-a73d-35d3367dbf9b'	System	27 Aug 2020 14:35:36
User entered '27 Aug 2020 09:35'	System	27 Aug 2020 14:35:36

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 7'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-28T09:31:25', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1a500c08-d8a8-4230-86de-e0e54f593123'	System	28 Aug 2020 14:31:50
User entered 'None (0)'	System	28 Aug 2020 14:31:50

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-28T09:31:28', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1a500c08-d8a8-4230-86de-e0e54f593123'	System	28 Aug 2020 14:31:50
User entered 'None (0)'	System	28 Aug 2020 14:31:50

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-28T09:31:30', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1a500c08-d8a8-4230-86de-e0e54f593123'	System	28 Aug 2020 14:31:50
User entered 'None (0)'	System	28 Aug 2020 14:31:50

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-28T09:31:34', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1a500c08-d8a8-4230-86de-e0e54f593123'	System	28 Aug 2020 14:31:50
User entered 'None (0)'	System	28 Aug 2020 14:31:50

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-28T09:31:38', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1a500c08-d8a8-4230-86de-e0e54f593123'	System	28 Aug 2020 14:31:50
User entered 'None (0)'	System	28 Aug 2020 14:31:50

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-28T09:31:40', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1a500c08-d8a8-4230-86de-e0e54f593123'	System	28 Aug 2020 14:31:50
User entered 'None (0)'	System	28 Aug 2020 14:31:50

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-28T09:31:44', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1a500c08-d8a8-4230-86de-e0e54f593123'	System	28 Aug 2020 14:31:50
User entered 'No (N)'	System	28 Aug 2020 14:31:50

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-08-28T09:31:46', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1a500c08-d8a8-4230-86de-e0e54f593123'	System	28 Aug 2020 14:31:50
User entered '28 Aug 2020 09:31'	System	28 Aug 2020 14:31:50

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 23:49:13

US3442068

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:39:48
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	02 Sep 2020 23:12:06

US3442068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:39:58
User entered '31 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	02 Sep 2020 23:12:06

US3442068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:40:01
User entered 'Contact Made (CONTACT MADE)'	Melody Dufrene (b) (4) (b) (4)	02 Sep 2020 23:12:06

US3442068

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:40:10
User entered empty.	Melody Dufrene (b) (4) (b) (4)	02 Sep 2020 23:12:06

US3442068

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:43:35
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	02 Sep 2020 23:12:14

US3442068

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'I'	System	02 Sep 2020 23:12:14

US3442068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:44:42
User entered 'Yes (Y)'		04 Sep 2020 16:41:45

US3442068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:44:51
User entered '4 Sep 2020'		04 Sep 2020 16:41:45

US3442068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:45:53
User entered 'Contact Made (CONTACT MADE)'		04 Sep 2020 16:41:45

US3442068

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:45:55
User entered empty.		04 Sep 2020 16:41:45

US3442068

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	17 Sep 2020 19:46:47
User entered 'Yes (Y)'		04 Sep 2020 16:41:52

US3442068

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'I'	System	04 Sep 2020 16:41:52

US3442068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:17:04
User entered 'Yes (Y)'		15 Sep 2020 16:05:58

US3442068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:17:04
User entered '14 Sep 2020'		15 Sep 2020 16:05:58

US3442068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:17:04
User entered 'Contact Made (CONTACT MADE)'		15 Sep 2020 16:05:58

US3442068

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:17:04
User entered empty.		15 Sep 2020 16:05:58

US3442068

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:17:08
User entered 'Yes (Y)'		15 Sep 2020 16:06:05

US3442068

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered '1'	System	15 Sep 2020 16:06:05

US3442068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:19:22
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 13:44:34

US3442068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:19:22
User entered '22 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 13:44:34

US3442068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:19:22
User entered 'Clinic (Clinic)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 13:44:34

US3442068

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'VISIT2'	System	22 Sep 2020 13:44:34

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User accepted default value 'Pre-Dose (PREDOSE)'		22 Sep 2020 22:11:11

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered 'Yes (Y)'		22 Sep 2020 22:11:11

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered '22 Sep 2020'		22 Sep 2020 22:11:11

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered '07:28'		22 Sep 2020 22:11:11

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered '22 Sep 2020 07:28'	System	22 Sep 2020 22:11:11

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered '97.6' F		22 Sep 2020 22:11:11

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered 'Oral (Oral)'		22 Sep 2020 22:11:11

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered empty.		22 Sep 2020 22:11:11

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered '61'		22 Sep 2020 22:11:11

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'bpm'	System	22 Sep 2020 22:11:11

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered '12'		22 Sep 2020 22:11:11

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'breaths/min'	System	22 Sep 2020 22:11:11

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered '150'		22 Sep 2020 22:11:11

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'mmHg'	System	22 Sep 2020 22:11:11

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered '78'		22 Sep 2020 22:11:11

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'mmHg'	System	22 Sep 2020 22:11:11

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User accepted default value 'Post-Dose (POSTDOSE)'		22 Sep 2020 22:13:43

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered 'Yes (Y)'		22 Sep 2020 22:13:43

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered '22 Sep 2020'		22 Sep 2020 22:13:43

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered '09:45'		22 Sep 2020 22:13:43

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered '22 Sep 2020 09:45'	System	22 Sep 2020 22:13:43

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered '97.2' F		22 Sep 2020 22:13:43

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User closed query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	System	22 Sep 2020 22:14:38
User opened query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	System	22 Sep 2020 22:13:43
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Sep 2020 22:13:43

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered empty; reason for change Data Entry Error		22 Sep 2020 22:14:38
User entered ''		22 Sep 2020 22:13:43

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered '58'		22 Sep 2020 22:13:43

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'bpm'	System	22 Sep 2020 22:13:43

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered '12'		22 Sep 2020 22:13:43

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'breaths/min'	System	22 Sep 2020 22:13:43

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered '134'		22 Sep 2020 22:13:43

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'mmHg'	System	22 Sep 2020 22:13:43

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:25:40
User entered '74'		22 Sep 2020 22:13:43

US3442068

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'mmHg'	System	22 Sep 2020 22:13:43

US3442068

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:21:49
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 13:44:42

US3442068

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:21:49
User entered '22 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 13:44:42

US3442068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:23:55
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:00:52

US3442068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:23:55
User entered empty.	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:00:52

US3442068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

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 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:23:55
User entered empty.	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:00:52

US3442068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 14:00:52

US3442068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:23:55
User entered '22 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:00:52

US3442068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:23:55
User entered '08:57'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:00:52

US3442068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered '22 Sep 2020 08:57'	System	22 Sep 2020 14:00:52

US3442068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:23:55
User entered 'Left Arm (LEFT ARM)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 14:00:52

US3442068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
DataPoint Verified.		10 Dec 2020 18:23:55
User entered 'ONCE'	System	22 Sep 2020 14:00:52

US3442068

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 14:00:52

US3442068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:27
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 13:45:08

US3442068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:27
User entered '22 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 13:45:08

US3442068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:27
User entered '07:52'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 13:45:08

US3442068

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered '22 Sep 2020 07:52'	System	22 Sep 2020 13:45:08

US3442068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:40:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:41
User entered '22 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 13:45:23

US3442068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 13:45:23

US3442068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:41
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 13:45:23

US3442068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:41
User entered '07:55'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 13:45:23

US3442068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:54

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered '22 Sep 2020 07:55'	System	22 Sep 2020 13:45:23

US3442068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 13:45:23

US3442068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 13:45:23

US3442068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:41
User entered empty.	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 13:45:23

US3442068

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered empty.	System	22 Sep 2020 13:45:23

US3442068

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:22:45
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 13:45:28

US3442068

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered '1'	System	22 Sep 2020 13:45:28

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T09:46:09', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ca4b9d2a-b65d-4f60-bdab-9ddc684dec00'	System	22 Sep 2020 14:46:35
User entered 'Yes (Y)'	System	22 Sep 2020 14:46:35

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T09:46:18', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ca4b9d2a-b65d-4f60-bdab-9ddc684dec00'	System	22 Sep 2020 14:46:35
User entered '97.2'	System	22 Sep 2020 14:46:35

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T09:46:23', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ca4b9d2a-b65d-4f60-bdab-9ddc684dec00'	System	22 Sep 2020 14:46:35
User entered 'No (N)'	System	22 Sep 2020 14:46:35

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T09:46:30', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ca4b9d2a-b65d-4f60-bdab-9ddc684dec00'	System	22 Sep 2020 14:46:35
User entered '22 Sep 2020 09:46'	System	22 Sep 2020 14:46:35

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '22 Sep 2020 09:17'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '22 Sep 2020 11:47'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T20:49:10', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '7ae65f11-72be-4e3d-b34c-8479d8364d8c'	System	23 Sep 2020 01:49:27
User entered 'Yes (Y)'	System	23 Sep 2020 01:49:27

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T20:49:16', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '7ae65f11-72be-4e3d-b34c-8479d8364d8c'	System	23 Sep 2020 01:49:27
User entered '97.2'	System	23 Sep 2020 01:49:27

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T20:49:19', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '7ae65f11-72be-4e3d-b34c-8479d8364d8c'	System	23 Sep 2020 01:49:27
User entered 'No (N)'	System	23 Sep 2020 01:49:27

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T20:49:24', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '7ae65f11-72be-4e3d-b34c-8479d8364d8c'	System	23 Sep 2020 01:49:27
User entered '22 Sep 2020 20:49'	System	23 Sep 2020 01:49:27

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '22 Sep 2020 12:42'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 2'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-23T12:36:13', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ceae505e-f3c5-439f-b106-ebc222c9ec2c'	System	23 Sep 2020 17:37:47
User entered 'Yes (Y)'	System	23 Sep 2020 17:37:47

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-23T12:37:36', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ceae505e-f3c5-439f-b106-ebc222c9ec2c'	System	23 Sep 2020 17:37:47
User entered '98.3'	System	23 Sep 2020 17:37:47

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-23T12:37:40', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ceae505e-f3c5-439f-b106-ebc222c9ec2c'	System	23 Sep 2020 17:37:47
User entered 'No (N)'	System	23 Sep 2020 17:37:47

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-23T12:37:44', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ceae505e-f3c5-439f-b106-ebc222c9ec2c'	System	23 Sep 2020 17:37:47
User entered '23 Sep 2020 12:37'	System	23 Sep 2020 17:37:47

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 3'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-24T22:43:25', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '45f5beb2-a7ef-4cd9-8029-939ed3af8007'	System	25 Sep 2020 03:43:50
User entered 'Yes (Y)'	System	25 Sep 2020 03:43:50

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-24T22:43:38', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '45f5beb2-a7ef-4cd9-8029-939ed3af8007'	System	25 Sep 2020 03:43:50
User entered '97.2'	System	25 Sep 2020 03:43:50

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-24T22:43:43', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '45f5beb2-a7ef-4cd9-8029-939ed3af8007'	System	25 Sep 2020 03:43:50
User entered 'No (N)'	System	25 Sep 2020 03:43:50

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-24T22:43:47', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '45f5beb2-a7ef-4cd9-8029-939ed3af8007'	System	25 Sep 2020 03:43:50
User entered '24 Sep 2020 22:43'	System	25 Sep 2020 03:43:50

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 4'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T19:55:34', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '85d45976-31c6-4a3d-860c-ec84662e5bff'	System	26 Sep 2020 00:56:56
User entered 'Yes (Y)'	System	26 Sep 2020 00:56:56

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T19:56:10', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '85d45976-31c6-4a3d-860c-ec84662e5bff'	System	26 Sep 2020 00:56:56
User entered '96.4'	System	26 Sep 2020 00:56:56

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T19:56:45', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '85d45976-31c6-4a3d-860c-ec84662e5bff'	System	26 Sep 2020 00:56:56
User entered 'No (N)'	System	26 Sep 2020 00:56:56

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T19:56:52', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '85d45976-31c6-4a3d-860c-ec84662e5bff'	System	26 Sep 2020 00:56:56
User entered '25 Sep 2020 19:56'	System	26 Sep 2020 00:56:56

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 5'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-26T17:04:27', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '5ecb9e50-9a45-42ab-ab24-c1e96ed89d19'	System	26 Sep 2020 22:04:59
User entered 'Yes (Y)'	System	26 Sep 2020 22:04:59

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-26T17:04:33', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '5ecb9e50-9a45-42ab-ab24-c1e96ed89d19' User entered '96.9'	System	26 Sep 2020 22:04:59
	System	26 Sep 2020 22:04:59

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-26T17:04:49', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '5ecb9e50-9a45-42ab-ab24-c1e96ed89d19'	System	26 Sep 2020 22:04:59
User entered 'No (N)'	System	26 Sep 2020 22:04:59

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-26T17:04:53', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '5ecb9e50-9a45-42ab-ab24-c1e96ed89d19'	System	26 Sep 2020 22:04:59
User entered '26 Sep 2020 17:04'	System	26 Sep 2020 22:04:59

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 6'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-27T20:54:42', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'b89bd2a1-8f5c-47b0-9202-e3d664a661fc'	System	28 Sep 2020 01:55:03
User entered 'Yes (Y)'	System	28 Sep 2020 01:55:03

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-27T20:54:50', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'b89bd2a1-8f5c-47b0-9202-e3d664a661fc'	System	28 Sep 2020 01:55:03
User entered '97.2'	System	28 Sep 2020 01:55:03

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-27T20:54:53', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'b89bd2a1-8f5c-47b0-9202-e3d664a661fc'	System	28 Sep 2020 01:55:03
User entered 'No (N)'	System	28 Sep 2020 01:55:03

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-27T20:54:59', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'b89bd2a1-8f5c-47b0-9202-e3d664a661fc'	System	28 Sep 2020 01:55:03
User entered '27 Sep 2020 20:54'	System	28 Sep 2020 01:55:03

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 7'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-28T13:17:56', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '76a24739-660b-4f27-af1f-cf9d6d036c7d'	System	28 Sep 2020 18:18:12
User entered 'Yes (Y)'	System	28 Sep 2020 18:18:12

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-28T13:18:01', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '76a24739-660b-4f27-af1f-cf9d6d036c7d' User entered '97.2'	System	28 Sep 2020 18:18:12

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-28T13:18:05', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '76a24739-660b-4f27-af1f-cf9d6d036c7d'	System	28 Sep 2020 18:18:12
User entered 'No (N)'	System	28 Sep 2020 18:18:12

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-28T13:18:08', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '76a24739-660b-4f27-af1f-cf9d6d036c7d'	System	28 Sep 2020 18:18:12
User entered '28 Sep 2020 13:18'	System	28 Sep 2020 18:18:12

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T09:47:28', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '400a8fb9-8356-4870-8d30-8e3dfca9baa2'	System	22 Sep 2020 14:47:54
User entered 'None (1)'	System	22 Sep 2020 14:47:54

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T09:47:37', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '400a8fb9-8356-4870-8d30-8e3dfca9baa2'	System	22 Sep 2020 14:47:54
User entered 'No (N)'	System	22 Sep 2020 14:47:54

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T09:47:41', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '400a8fb9-8356-4870-8d30-8e3dfca9baa2'	System	22 Sep 2020 14:47:54
User entered 'No (N)'	System	22 Sep 2020 14:47:54

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T09:47:48', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '400a8fb9-8356-4870-8d30-8e3dfca9baa2'	System	22 Sep 2020 14:47:54
User entered 'None (1)'	System	22 Sep 2020 14:47:54

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T09:47:52', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '400a8fb9-8356-4870-8d30-8e3dfca9baa2'	System	22 Sep 2020 14:47:54
User entered '22 Sep 2020 09:47'	System	22 Sep 2020 14:47:54

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '22 Sep 2020 09:17'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '22 Sep 2020 11:47'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T20:49:38', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '2d88c397-d079-4151-a22e-b7704dce629e'	System	23 Sep 2020 02:05:25
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 02:05:25

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T20:49:50', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '2d88c397-d079-4151-a22e-b7704dce629e'	System	23 Sep 2020 02:05:25
User entered 'Yes (Y)'	System	23 Sep 2020 02:05:25

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T21:04:31', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '2d88c397-d079-4151-a22e-b7704dce629e'	System	23 Sep 2020 02:05:25
User entered '5'	System	23 Sep 2020 02:05:25

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T21:04:35', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '2d88c397-d079-4151-a22e-b7704dce629e'	System	23 Sep 2020 02:05:25
User entered 'Yes (Y)'	System	23 Sep 2020 02:05:25

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T21:04:48', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '2d88c397-d079-4151-a22e-b7704dce629e'	System	23 Sep 2020 02:05:25
User entered '5'	System	23 Sep 2020 02:05:25

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T21:04:52', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '2d88c397-d079-4151-a22e-b7704dce629e'	System	23 Sep 2020 02:05:25
User entered 'None (1)'	System	23 Sep 2020 02:05:25

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T21:04:56', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '2d88c397-d079-4151-a22e-b7704dce629e'	System	23 Sep 2020 02:05:25
User entered '22 Sep 2020 21:04'	System	23 Sep 2020 02:05:25

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '22 Sep 2020 12:42'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 2'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-23T12:37:53', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '18be9bc2-5a6b-4f0c-aa8f-c0ccfc0deb2d'	System	23 Sep 2020 17:38:25
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 17:38:25

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-23T12:37:56', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '18be9bc2-5a6b-4f0c-aa8f-c0ccfc0deb2d'	System	23 Sep 2020 17:38:25
User entered 'No (N)'	System	23 Sep 2020 17:38:25

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-23T12:37:59', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '18be9bc2-5a6b-4f0c-aa8f-c0ccfc0deb2d'	System	23 Sep 2020 17:38:25
User entered 'Yes (Y)'	System	23 Sep 2020 17:38:25

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

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)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-23T12:38:14', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '18be9bc2-5a6b-4f0c-aa8f-c0ccfc0deb2d' User entered '5'	System	23 Sep 2020 17:38:25
	System	23 Sep 2020 17:38:25

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-23T12:38:17', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '18be9bc2-5a6b-4f0c-aa8f-c0ccfc0deb2d'	System	23 Sep 2020 17:38:25
User entered 'None (1)'	System	23 Sep 2020 17:38:25

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-23T12:38:20', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '18be9bc2-5a6b-4f0c-aa8f-c0ccfc0deb2d'	System	23 Sep 2020 17:38:25
User entered '23 Sep 2020 12:38'	System	23 Sep 2020 17:38:25

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 3'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T05:19:21', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '38c1346b-bd25-4ca9-b4d6-5475c8872e63'	System	25 Sep 2020 10:20:06
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 10:20:06

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T05:19:24', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '38c1346b-bd25-4ca9-b4d6-5475c8872e63'	System	25 Sep 2020 10:20:06
User entered 'No (N)'	System	25 Sep 2020 10:20:06

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T05:19:34', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '38c1346b-bd25-4ca9-b4d6-5475c8872e63'	System	25 Sep 2020 10:20:06
User entered 'Yes (Y)'	System	25 Sep 2020 10:20:06

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

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)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T05:19:49', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '38c1346b-bd25-4ca9-b4d6-5475c8872e63'	System	25 Sep 2020 10:20:06
User entered '3'	System	25 Sep 2020 10:20:06

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T05:19:58', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '38c1346b-bd25-4ca9-b4d6-5475c8872e63'	System	25 Sep 2020 10:20:06
User entered 'None (1)'	System	25 Sep 2020 10:20:06

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T05:20:01', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '38c1346b-bd25-4ca9-b4d6-5475c8872e63'	System	25 Sep 2020 10:20:06
User entered '25 Sep 2020 05:20'	System	25 Sep 2020 10:20:06

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 4'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T19:57:20', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'c6d210c5-9e92-403f-8573-c597fa422a00'	System	26 Sep 2020 00:57:50
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 00:57:50

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T19:57:25', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'c6d210c5-9e92-403f-8573-c597fa422a00'	System	26 Sep 2020 00:57:50
User entered 'No (N)'	System	26 Sep 2020 00:57:50

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T19:57:29', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'c6d210c5-9e92-403f-8573-c597fa422a00'	System	26 Sep 2020 00:57:50
User entered 'Yes (Y)'	System	26 Sep 2020 00:57:50

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

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)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T19:57:36', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'c6d210c5-9e92-403f-8573-c597fa422a00'	System	26 Sep 2020 00:57:50
User entered '1'	System	26 Sep 2020 00:57:50

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T19:57:39', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'c6d210c5-9e92-403f-8573-c597fa422a00'	System	26 Sep 2020 00:57:50
User entered 'None (1)'	System	26 Sep 2020 00:57:50

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T19:57:47', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'c6d210c5-9e92-403f-8573-c597fa422a00'	System	26 Sep 2020 00:57:50
User entered '25 Sep 2020 19:57'	System	26 Sep 2020 00:57:50

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 5'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-26T17:05:01', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '9772460f-1df5-4b38-b51b-89159d4eaaf0'	System	26 Sep 2020 22:05:21
User entered 'None (1)'	System	26 Sep 2020 22:05:21

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-26T17:05:04', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '9772460f-1df5-4b38-b51b-89159d4eaaf0'	System	26 Sep 2020 22:05:21
User entered 'No (N)'	System	26 Sep 2020 22:05:21

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-26T17:05:07', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '9772460f-1df5-4b38-b51b-89159d4eaaf0'	System	26 Sep 2020 22:05:21
User entered 'No (N)'	System	26 Sep 2020 22:05:21

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-26T17:05:10', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '9772460f-1df5-4b38-b51b-89159d4eaaf0'	System	26 Sep 2020 22:05:21
User entered 'None (1)'	System	26 Sep 2020 22:05:21

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-26T17:05:18', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '9772460f-1df5-4b38-b51b-89159d4eaaf0'	System	26 Sep 2020 22:05:21
User entered '26 Sep 2020 17:05'	System	26 Sep 2020 22:05:21

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 6'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-27T20:55:05', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '01517adb-80f8-469b-befe-05aa60b50712'	System	28 Sep 2020 01:55:18
User entered 'None (1)'	System	28 Sep 2020 01:55:18

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-27T20:55:07', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '01517adb-80f8-469b-befe-05aa60b50712'	System	28 Sep 2020 01:55:18
User entered 'No (N)'	System	28 Sep 2020 01:55:18

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-27T20:55:10', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '01517adb-80f8-469b-befe-05aa60b50712'	System	28 Sep 2020 01:55:18
User entered 'No (N)'	System	28 Sep 2020 01:55:18

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-27T20:55:12', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '01517adb-80f8-469b-befe-05aa60b50712'	System	28 Sep 2020 01:55:18
User entered 'None (1)'	System	28 Sep 2020 01:55:18

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-27T20:55:14', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '01517adb-80f8-469b-befe-05aa60b50712'	System	28 Sep 2020 01:55:18
User entered '27 Sep 2020 20:55'	System	28 Sep 2020 01:55:18

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 7'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-28T13:18:13', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '0ae49041-6ca9-4543-8d12-79c7eb599fd9'	System	28 Sep 2020 18:18:58
User entered 'None (1)'	System	28 Sep 2020 18:18:58

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-28T13:18:17', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '0ae49041-6ca9-4543-8d12-79c7eb599fd9'	System	28 Sep 2020 18:18:58
User entered 'No (N)'	System	28 Sep 2020 18:18:58

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-28T13:18:28', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '0ae49041-6ca9-4543-8d12-79c7eb599fd9'	System	28 Sep 2020 18:18:58
User entered 'No (N)'	System	28 Sep 2020 18:18:58

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-28T13:18:31', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '0ae49041-6ca9-4543-8d12-79c7eb599fd9'	System	28 Sep 2020 18:18:58
User entered 'None (1)'	System	28 Sep 2020 18:18:58

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-28T13:18:33', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '0ae49041-6ca9-4543-8d12-79c7eb599fd9'	System	28 Sep 2020 18:18:58
User entered '28 Sep 2020 13:18'	System	28 Sep 2020 18:18:58

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T09:47:59', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'e6073a0f-19b2-4620-b073-0cd906bf1949'	System	22 Sep 2020 14:48:28
User entered 'None (0)'	System	22 Sep 2020 14:48:28

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T09:48:05', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'e6073a0f-19b2-4620-b073-0cd906bf1949'	System	22 Sep 2020 14:48:28
User entered 'None (0)'	System	22 Sep 2020 14:48:28

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T09:48:08', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'e6073a0f-19b2-4620-b073-0cd906bf1949'	System	22 Sep 2020 14:48:28
User entered 'None (0)'	System	22 Sep 2020 14:48:28

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T09:48:11', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'e6073a0f-19b2-4620-b073-0cd906bf1949'	System	22 Sep 2020 14:48:28
User entered 'None (0)'	System	22 Sep 2020 14:48:28

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T09:48:14', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'e6073a0f-19b2-4620-b073-0cd906bf1949'	System	22 Sep 2020 14:48:28
User entered 'None (0)'	System	22 Sep 2020 14:48:28

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T09:48:17', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'e6073a0f-19b2-4620-b073-0cd906bf1949'	System	22 Sep 2020 14:48:28
User entered 'None (0)'	System	22 Sep 2020 14:48:28

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T09:48:21', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'e6073a0f-19b2-4620-b073-0cd906bf1949'	System	22 Sep 2020 14:48:28
User entered 'No (N)'	System	22 Sep 2020 14:48:28

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T09:48:24', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'e6073a0f-19b2-4620-b073-0cd906bf1949'	System	22 Sep 2020 14:48:28
User entered '22 Sep 2020 09:48'	System	22 Sep 2020 14:48:28

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '22 Sep 2020 09:17'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '22 Sep 2020 11:47'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T21:05:01', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '94a38a91-6ff6-4b82-8996-30c6838c4482'	System	23 Sep 2020 02:05:39
User entered 'None (0)'	System	23 Sep 2020 02:05:39

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T21:05:04', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '94a38a91-6ff6-4b82-8996-30c6838c4482'	System	23 Sep 2020 02:05:39
User entered 'None (0)'	System	23 Sep 2020 02:05:39

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T21:05:07', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '94a38a91-6ff6-4b82-8996-30c6838c4482'	System	23 Sep 2020 02:05:39
User entered 'None (0)'	System	23 Sep 2020 02:05:39

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T21:05:10', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '94a38a91-6ff6-4b82-8996-30c6838c4482'	System	23 Sep 2020 02:05:39
User entered 'None (0)'	System	23 Sep 2020 02:05:39

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T21:05:12', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '94a38a91-6ff6-4b82-8996-30c6838c4482'	System	23 Sep 2020 02:05:39
User entered 'None (0)'	System	23 Sep 2020 02:05:39

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T21:05:14', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '94a38a91-6ff6-4b82-8996-30c6838c4482'	System	23 Sep 2020 02:05:39
User entered 'None (0)'	System	23 Sep 2020 02:05:39

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T21:05:17', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '94a38a91-6ff6-4b82-8996-30c6838c4482'	System	23 Sep 2020 02:05:39
User entered 'No (N)'	System	23 Sep 2020 02:05:39

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-22T21:05:20', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '94a38a91-6ff6-4b82-8996-30c6838c4482'	System	23 Sep 2020 02:05:39
User entered '22 Sep 2020 21:05'	System	23 Sep 2020 02:05:39

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '22 Sep 2020 12:42'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 2'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-23T12:38:27', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'b82bffc6-ff7e-46d9-85fc-af1284b22da6'	System	23 Sep 2020 17:39:04
User entered 'None (0)'	System	23 Sep 2020 17:39:04

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-23T12:38:38', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'b82bffc6-ff7e-46d9-85fc-af1284b22da6'	System	23 Sep 2020 17:39:04
User entered 'No interference with activity (1)'	System	23 Sep 2020 17:39:04

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-23T12:38:43', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'b82bffc6-ff7e-46d9-85fc-af1284b22da6'	System	23 Sep 2020 17:39:04
User entered 'None (0)'	System	23 Sep 2020 17:39:04

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-23T12:38:46', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'b82bffc6-ff7e-46d9-85fc-af1284b22da6'	System	23 Sep 2020 17:39:04
User entered 'None (0)'	System	23 Sep 2020 17:39:04

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-23T12:38:48', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'b82bffc6-ff7e-46d9-85fc-af1284b22da6'	System	23 Sep 2020 17:39:04
User entered 'None (0)'	System	23 Sep 2020 17:39:04

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-23T12:38:51', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'b82bffc6-ff7e-46d9-85fc-af1284b22da6'	System	23 Sep 2020 17:39:04
User entered 'None (0)'	System	23 Sep 2020 17:39:04

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-23T12:38:56', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'b82bffc6-ff7e-46d9-85fc-af1284b22da6'	System	23 Sep 2020 17:39:04
User entered 'No (N)'	System	23 Sep 2020 17:39:04

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-23T12:38:59', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'b82bffc6-ff7e-46d9-85fc-af1284b22da6'	System	23 Sep 2020 17:39:04
User entered '23 Sep 2020 12:38'	System	23 Sep 2020 17:39:04

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 3'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T05:20:14', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1db6b58f-7228-4e0d-b035-c3b07b60a4d6'	System	25 Sep 2020 10:20:49
User entered 'None (0)'	System	25 Sep 2020 10:20:49

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T05:20:17', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1db6b58f-7228-4e0d-b035-c3b07b60a4d6'	System	25 Sep 2020 10:20:49
User entered 'No interference with activity (1)'	System	25 Sep 2020 10:20:49

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T05:20:25', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1db6b58f-7228-4e0d-b035-c3b07b60a4d6'	System	25 Sep 2020 10:20:49
User entered 'No interference with activity (1)'	System	25 Sep 2020 10:20:49

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T05:20:29', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1db6b58f-7228-4e0d-b035-c3b07b60a4d6'	System	25 Sep 2020 10:20:49
User entered 'None (0)'	System	25 Sep 2020 10:20:49

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T05:20:32', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1db6b58f-7228-4e0d-b035-c3b07b60a4d6'	System	25 Sep 2020 10:20:49
User entered 'None (0)'	System	25 Sep 2020 10:20:49

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T05:20:35', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1db6b58f-7228-4e0d-b035-c3b07b60a4d6'	System	25 Sep 2020 10:20:49
User entered 'None (0)'	System	25 Sep 2020 10:20:49

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T05:20:41', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1db6b58f-7228-4e0d-b035-c3b07b60a4d6'	System	25 Sep 2020 10:20:49
User entered 'No (N)'	System	25 Sep 2020 10:20:49

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T05:20:44', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1db6b58f-7228-4e0d-b035-c3b07b60a4d6'	System	25 Sep 2020 10:20:49
User entered '25 Sep 2020 05:20'	System	25 Sep 2020 10:20:49

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 4'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T19:57:51', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'c80e6bd1-4ae9-4923-857a-156b336e85b9'	System	26 Sep 2020 00:58:11
User entered 'None (0)'	System	26 Sep 2020 00:58:11

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T19:57:53', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'c80e6bd1-4ae9-4923-857a-156b336e85b9'	System	26 Sep 2020 00:58:11
User entered 'None (0)'	System	26 Sep 2020 00:58:11

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T19:57:55', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'c80e6bd1-4ae9-4923-857a-156b336e85b9'	System	26 Sep 2020 00:58:11
User entered 'None (0)'	System	26 Sep 2020 00:58:11

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T19:57:57', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'c80e6bd1-4ae9-4923-857a-156b336e85b9'	System	26 Sep 2020 00:58:11
User entered 'None (0)'	System	26 Sep 2020 00:58:11

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T19:57:58', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'c80e6bd1-4ae9-4923-857a-156b336e85b9'	System	26 Sep 2020 00:58:11
User entered 'None (0)'	System	26 Sep 2020 00:58:11

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T19:58:00', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'c80e6bd1-4ae9-4923-857a-156b336e85b9'	System	26 Sep 2020 00:58:11
User entered 'None (0)'	System	26 Sep 2020 00:58:11

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T19:58:03', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'c80e6bd1-4ae9-4923-857a-156b336e85b9'	System	26 Sep 2020 00:58:11
User entered 'No (N)'	System	26 Sep 2020 00:58:11

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-25T19:58:07', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'c80e6bd1-4ae9-4923-857a-156b336e85b9'	System	26 Sep 2020 00:58:11
User entered '25 Sep 2020 19:58'	System	26 Sep 2020 00:58:11

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 5'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-26T17:05:24', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '13992da1-d2d4-4d15-83d1-a09d2073b952'	System	26 Sep 2020 22:06:03
User entered 'None (0)'	System	26 Sep 2020 22:06:03

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-26T17:05:31', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '13992da1-d2d4-4d15-83d1-a09d2073b952'	System	26 Sep 2020 22:06:03
User entered 'No interference with activity (1)'	System	26 Sep 2020 22:06:03

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-26T17:05:38', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '13992da1-d2d4-4d15-83d1-a09d2073b952'	System	26 Sep 2020 22:06:03
User entered 'None (0)'	System	26 Sep 2020 22:06:03

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-26T17:05:42', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '13992da1-d2d4-4d15-83d1-a09d2073b952'	System	26 Sep 2020 22:06:03
User entered 'None (0)'	System	26 Sep 2020 22:06:03

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-26T17:05:44', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '13992da1-d2d4-4d15-83d1-a09d2073b952'	System	26 Sep 2020 22:06:03
User entered 'None (0)'	System	26 Sep 2020 22:06:03

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-26T17:05:47', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '13992da1-d2d4-4d15-83d1-a09d2073b952'	System	26 Sep 2020 22:06:03
User entered 'None (0)'	System	26 Sep 2020 22:06:03

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-26T17:05:56', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '13992da1-d2d4-4d15-83d1-a09d2073b952'	System	26 Sep 2020 22:06:03
User entered 'No (N)'	System	26 Sep 2020 22:06:03

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-26T17:05:59', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '13992da1-d2d4-4d15-83d1-a09d2073b952'	System	26 Sep 2020 22:06:03
User entered '26 Sep 2020 17:05'	System	26 Sep 2020 22:06:03

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 6'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-27T20:55:18', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '95ec594d-350b-42a5-a6b9-8acd98068866'	System	28 Sep 2020 01:55:42
User entered 'None (0)'	System	28 Sep 2020 01:55:42

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-27T20:55:20', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '95ec594d-350b-42a5-a6b9-8acd98068866'	System	28 Sep 2020 01:55:42
User entered 'None (0)'	System	28 Sep 2020 01:55:42

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-27T20:55:22', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '95ec594d-350b-42a5-a6b9-8acd98068866'	System	28 Sep 2020 01:55:42
User entered 'None (0)'	System	28 Sep 2020 01:55:42

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-27T20:55:25', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '95ec594d-350b-42a5-a6b9-8acd98068866'	System	28 Sep 2020 01:55:42
User entered 'None (0)'	System	28 Sep 2020 01:55:42

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-27T20:55:29', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '95ec594d-350b-42a5-a6b9-8acd98068866'	System	28 Sep 2020 01:55:42
User entered 'None (0)'	System	28 Sep 2020 01:55:42

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-27T20:55:32', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '95ec594d-350b-42a5-a6b9-8acd98068866'	System	28 Sep 2020 01:55:42
User entered 'None (0)'	System	28 Sep 2020 01:55:42

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-27T20:55:34', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '95ec594d-350b-42a5-a6b9-8acd98068866'	System	28 Sep 2020 01:55:42
User entered 'No (N)'	System	28 Sep 2020 01:55:42

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-27T20:55:37', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '95ec594d-350b-42a5-a6b9-8acd98068866'	System	28 Sep 2020 01:55:42
User entered '27 Sep 2020 20:55'	System	28 Sep 2020 01:55:42

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	22 Sep 2020 14:00:52
User entered 'Day 7'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-28T13:18:37', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '93d1df34-579c-41d5-81a6-060d77047830'	System	28 Sep 2020 18:19:05
User entered 'None (0)'	System	28 Sep 2020 18:19:05

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-28T13:18:39', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '93d1df34-579c-41d5-81a6-060d77047830'	System	28 Sep 2020 18:19:05
User entered 'None (0)'	System	28 Sep 2020 18:19:05

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-28T13:18:41', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '93d1df34-579c-41d5-81a6-060d77047830'	System	28 Sep 2020 18:19:05
User entered 'None (0)'	System	28 Sep 2020 18:19:05

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-28T13:18:43', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '93d1df34-579c-41d5-81a6-060d77047830'	System	28 Sep 2020 18:19:05
User entered 'None (0)'	System	28 Sep 2020 18:19:05

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-28T13:18:45', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '93d1df34-579c-41d5-81a6-060d77047830'	System	28 Sep 2020 18:19:05
User entered 'None (0)'	System	28 Sep 2020 18:19:05

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-28T13:18:47', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '93d1df34-579c-41d5-81a6-060d77047830'	System	28 Sep 2020 18:19:05
User entered 'None (0)'	System	28 Sep 2020 18:19:05

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-28T13:18:51', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '93d1df34-579c-41d5-81a6-060d77047830'	System	28 Sep 2020 18:19:05
User entered 'No (N)'	System	28 Sep 2020 18:19:05

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-09-28T13:18:53', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '93d1df34-579c-41d5-81a6-060d77047830'	System	28 Sep 2020 18:19:05
User entered '28 Sep 2020 13:18'	System	28 Sep 2020 18:19:05

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 14:00:52

US3442068

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 14:00:52

US3442068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:27:51
User entered 'Yes (Y)'		29 Sep 2020 21:47:41

US3442068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:27:51
User entered '29 Sep 2020'		29 Sep 2020 21:47:41

US3442068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:27:51
User entered 'Contact Made (CONTACT MADE)'		29 Sep 2020 21:47:41

US3442068

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:27:51
User entered empty.		29 Sep 2020 21:47:41

US3442068

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:30:36
User entered 'Yes (Y)'		29 Sep 2020 21:47:47

US3442068

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'I'	System	29 Sep 2020 21:47:47

US3442068

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:32:11
User entered 'Yes (Y)'		06 Oct 2020 21:19:46

US3442068

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:32:11
User entered '6 Oct 2020'		06 Oct 2020 21:19:46

US3442068

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:32:11
User entered 'Contact Made (CONTACT MADE)'		06 Oct 2020 21:19:46

US3442068

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:32:11
User entered empty.		06 Oct 2020 21:19:46

US3442068

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:32:15
User entered 'Yes (Y)'		06 Oct 2020 21:19:53

US3442068

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'I'	System	06 Oct 2020 21:19:53

US3442068

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:37:59
User entered 'Yes (Y)'		15 Oct 2020 22:16:33

US3442068

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:37:59
User entered '13 Oct 2020'		15 Oct 2020 22:16:33

US3442068

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:37:59
User entered 'Contact Made (CONTACT MADE)'		15 Oct 2020 22:16:33

US3442068

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:37:59
User entered empty.		15 Oct 2020 22:16:33

US3442068

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:38:02
User entered 'Yes (Y)'		15 Oct 2020 22:16:39

US3442068

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'I'	System	15 Oct 2020 22:16:39

US3442068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:38:27
User entered 'Yes (Y)'		19 Oct 2020 21:04:02

US3442068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:38:27
User entered '19 Oct 2020'		19 Oct 2020 21:04:02

US3442068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:38:27
User entered 'Clinic (Clinic)'		19 Oct 2020 21:04:02

US3442068

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'VISIT3'	System	19 Oct 2020 21:04:02

US3442068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:38:49
User entered 'No (N)'		19 Oct 2020 21:03:53

US3442068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:38:49
User entered empty.		19 Oct 2020 21:03:53

US3442068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:38:49
User entered empty.		19 Oct 2020 21:03:53

US3442068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered empty.	System	19 Oct 2020 21:03:53

US3442068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:38:49
User entered empty.		19 Oct 2020 21:03:53

US3442068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:38:49
User entered empty.		19 Oct 2020 21:03:53

US3442068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:38:49
User entered empty.		19 Oct 2020 21:03:53

US3442068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:38:49
User entered empty.		19 Oct 2020 21:03:53

US3442068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered empty.	System	19 Oct 2020 21:03:53

US3442068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:38:49
User entered empty.		19 Oct 2020 21:03:53

US3442068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered empty.	System	19 Oct 2020 21:03:53

US3442068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:38:49
User entered empty.		19 Oct 2020 21:03:53

US3442068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered empty.	System	19 Oct 2020 21:03:53

US3442068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:38:49
User entered empty.		19 Oct 2020 21:03:53

US3442068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered empty.	System	19 Oct 2020 21:03:53

US3442068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32

US3442068

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32

US3442068

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:38:56
User entered 'No (N)'		19 Oct 2020 21:04:12

US3442068

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:38:56
User entered empty.		19 Oct 2020 21:04:12

US3442068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:39:53
User entered 'Yes (Y)'		19 Oct 2020 21:04:25

US3442068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:39:53
User entered '19 Oct 2020'		19 Oct 2020 21:04:25

US3442068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:39:53
User entered '08:45'		19 Oct 2020 21:04:25

US3442068

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered '19 Oct 2020 08:45'	System	19 Oct 2020 21:04:25

US3442068

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:39:58
User entered 'Yes (Y)'		19 Oct 2020 21:03:47

US3442068

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered '1'	System	19 Oct 2020 21:03:47

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 64'	System	21 Aug 2020 23:49:13

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07
Data entry locked.	System	21 Aug 2020 23:49:13
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 23:49:13

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:06:07
Data entry locked.	System	21 Aug 2020 23:49:13
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 71'	System	21 Aug 2020 23:49:13

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-10-31T18:03:59', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '487b6da5-87a7-4b1c-b78e-53d1f37ca10f'	System	31 Oct 2020 23:04:29
User entered 'No (N)'	System	31 Oct 2020 23:04:29

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-10-31T18:04:08', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '487b6da5-87a7-4b1c-b78e-53d1f37ca10f'	System	31 Oct 2020 23:04:29
User entered 'Yes (Y)'	System	31 Oct 2020 23:04:29

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Please 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)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-10-31T18:04:15', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '487b6da5-87a7-4b1c-b78e-53d1f37ca10f'	System	31 Oct 2020 23:04:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Oct 2020 23:04:29

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-10-31T18:04:20', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '487b6da5-87a7-4b1c-b78e-53d1f37ca10f'	System	31 Oct 2020 23:04:29
User entered '31 Oct 2020 18:04:20'	System	31 Oct 2020 23:04:29

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 23:49:13

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 78'	System	21 Aug 2020 23:49:13

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-11-04T11:03:12', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '8f80eae4-47fa-46d9-945f-164290a77899'	System	04 Nov 2020 17:06:33
User entered 'No (N)'	System	04 Nov 2020 17:06:33

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-11-04T11:03:41', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '8f80eae4-47fa-46d9-945f-164290a77899'	System	04 Nov 2020 17:06:33
User entered 'No (N)'	System	04 Nov 2020 17:06:33

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-11-04T11:03:47', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '8f80eae4-47fa-46d9-945f-164290a77899'	System	04 Nov 2020 17:06:33
User entered '04 Nov 2020 11:03:47'	System	04 Nov 2020 17:06:33

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 23:49:13

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered 'Day 92'	System	21 Aug 2020 23:49:13

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-11-18T12:51:10', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '7fe48f26-e78b-497a-bb8c-503cdb7274b1'	System	18 Nov 2020 18:51:39
User entered 'No (N)'	System	18 Nov 2020 18:51:39

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-11-18T12:51:18', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '7fe48f26-e78b-497a-bb8c-503cdb7274b1'	System	18 Nov 2020 18:51:39
User entered 'Yes (Y)'	System	18 Nov 2020 18:51:39

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

Please 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)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-11-18T12:51:22', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '7fe48f26-e78b-497a-bb8c-503cdb7274b1'	System	18 Nov 2020 18:51:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Nov 2020 18:51:39

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-11-18T12:51:26', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '7fe48f26-e78b-497a-bb8c-503cdb7274b1'	System	18 Nov 2020 18:51:39
User entered '18 Nov 2020 12:51:26'	System	18 Nov 2020 18:51:39

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 23:49:13

US3442068

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:10:31
Data entry locked.	System	21 Aug 2020 23:49:13
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 23:49:13

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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 (082f674fce1dc942)', Time: '2020-11-22T11:10:54', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '11f81570-d7f5-4579-a1f9-60e60dc54fdd'	System	22 Nov 2020 17:11:13
User entered 'No (N)'	System	22 Nov 2020 17:11:13

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

Have you been exposed to someone with 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 (082f674fce1dc942)', Time: '2020-11-22T11:11:06', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '11f81570-d7f5-4579-a1f9-60e60dc54fdd'	System	22 Nov 2020 17:11:13
User entered 'No (N)'	System	22 Nov 2020 17:11:13

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-11-22T11:11:10', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '11f81570-d7f5-4579-a1f9-60e60dc54fdd'	System	22 Nov 2020 17:11:13
User entered '22 Nov 2020 11:11:10'	System	22 Nov 2020 17:11:13

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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 (082f674fce1dc942)', Time: '2020-11-29T16:16:40', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1aa42a65-87c3-4774-8547-de4a9b67db28'	System	29 Nov 2020 22:17:04
User entered 'No (N)'	System	29 Nov 2020 22:17:04

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Have you been exposed to someone with 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 (082f674fce1dc942)', Time: '2020-11-29T16:16:55', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1aa42a65-87c3-4774-8547-de4a9b67db28'	System	29 Nov 2020 22:17:04
User entered 'No (N)'	System	29 Nov 2020 22:17:04

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-11-29T16:16:58', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '1aa42a65-87c3-4774-8547-de4a9b67db28' User entered '29 Nov 2020 16:16:58'	System	29 Nov 2020 22:17:04
	System	29 Nov 2020 22:17:04

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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 (082f674fce1dc942)', Time: '2020-12-07T09:44:21', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '36310fdc-8d94-46d3-ab26-c85220b2ba38'	System	07 Dec 2020 15:44:35
User entered 'No (N)'	System	07 Dec 2020 15:44:35

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

Have you been exposed to someone with 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 (082f674fce1dc942)', Time: '2020-12-07T09:44:25', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '36310fdc-8d94-46d3-ab26-c85220b2ba38'	System	07 Dec 2020 15:44:35
User entered 'No (N)'	System	07 Dec 2020 15:44:35

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-12-07T09:44:29', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '36310fdc-8d94-46d3-ab26-c85220b2ba38'	System	07 Dec 2020 15:44:35
User entered '07 Dec 2020 09:44:29'	System	07 Dec 2020 15:44:35

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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 (082f674fce1dc942)', Time: '2020-12-15T13:11:43', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '635d78f1-950c-4f75-8334-52b15098fb0e'	System	15 Dec 2020 19:12:11
User entered 'Yes (Y)'	System	15 Dec 2020 19:12:11

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

Have you been exposed to someone with 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 (082f674fce1dc942)', Time: '2020-12-15T13:11:49', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '635d78f1-950c-4f75-8334-52b15098fb0e'	System	15 Dec 2020 19:12:11
User entered 'No (N)'	System	15 Dec 2020 19:12:11

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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 (082f674fce1dc942)', Time: '2020-12-15T13:11:52', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '635d78f1-950c-4f75-8334-52b15098fb0e'	System	15 Dec 2020 19:12:11
User entered 'No (N)'	System	15 Dec 2020 19:12:11

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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 (082f674fce1dc942)', Time: '2020-12-15T13:12:03', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '635d78f1-950c-4f75-8334-52b15098fb0e'	System	15 Dec 2020 19:12:11
User entered 'No (N)'	System	15 Dec 2020 19:12:11

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-12-15T13:12:07', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '635d78f1-950c-4f75-8334-52b15098fb0e' User entered '15 Dec 2020 13:12:07'	System	15 Dec 2020 19:12:11
	System	15 Dec 2020 19:12:11

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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 (082f674fce1dc942)', Time: '2020-12-21T17:11:09', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '8c0ddd77-7347-43d8-b97c-3e90240a0379'	System	21 Dec 2020 23:12:27
User entered 'No (N)'	System	21 Dec 2020 23:12:27

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

Have you been exposed to someone with 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 (082f674fce1dc942)', Time: '2020-12-21T17:12:17', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '8c0ddd77-7347-43d8-b97c-3e90240a0379'	System	21 Dec 2020 23:12:27
User entered 'No (N)'	System	21 Dec 2020 23:12:27

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-12-21T17:12:24', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '8c0ddd77-7347-43d8-b97c-3e90240a0379' User entered '21 Dec 2020 17:12:24'	System	21 Dec 2020 23:12:27
	System	21 Dec 2020 23:12:27

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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 (082f674fce1dc942)', Time: '2020-12-27T07:12:32', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '6eec0598-eafc-4dc3-b77c-723219b9cd64'	System	27 Dec 2020 13:12:43
User entered 'No (N)'	System	27 Dec 2020 13:12:43

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

Have you been exposed to someone with 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 (082f674fce1dc942)', Time: '2020-12-27T07:12:37', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '6eec0598-eafc-4dc3-b77c-723219b9cd64'	System	27 Dec 2020 13:12:43
User entered 'No (N)'	System	27 Dec 2020 13:12:43

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2020-12-27T07:12:41', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '6eec0598-eafc-4dc3-b77c-723219b9cd64'	System	27 Dec 2020 13:12:43
User entered '27 Dec 2020 07:12:41'	System	27 Dec 2020 13:12:43

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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 (082f674fce1dc942)', Time: '2021-01-07T10:56:21', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '83c4d079-b05c-48e8-ab75-027741fe0d17'	System	07 Jan 2021 16:56:42
User entered 'No (N)'	System	07 Jan 2021 16:56:42

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

Have you been exposed to someone with 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 (082f674fce1dc942)', Time: '2021-01-07T10:56:29', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '83c4d079-b05c-48e8-ab75-027741fe0d17'	System	07 Jan 2021 16:56:42
User entered 'No (N)'	System	07 Jan 2021 16:56:42

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2021-01-07T10:56:38', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '83c4d079-b05c-48e8-ab75-027741fe0d17'	System	07 Jan 2021 16:56:42
User entered '07 Jan 2021 10:56:38'	System	07 Jan 2021 16:56:42

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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 (082f674fce1dc942)', Time: '2021-01-10T06:46:28', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '5155aaec-d227-4e78-9379-c033a750456b'	System	10 Jan 2021 12:46:42
User entered 'No (N)'	System	10 Jan 2021 12:46:42

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

Have you been exposed to someone with 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 (082f674fce1dc942)', Time: '2021-01-10T06:46:32', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '5155aaec-d227-4e78-9379-c033a750456b'	System	10 Jan 2021 12:46:42
User entered 'No (N)'	System	10 Jan 2021 12:46:42

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2021-01-10T06:46:35', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '5155aaec-d227-4e78-9379-c033a750456b' User entered '10 Jan 2021 06:46:35'	System	10 Jan 2021 12:46:42
	System	10 Jan 2021 12:46:42

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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 (082f674fce1dc942)', Time: '2021-01-17T07:09:12', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '5b29206a-e3c6-4411-951f-71798a90d911'	System	17 Jan 2021 13:09:21
User entered 'No (N)'	System	17 Jan 2021 13:09:21

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

Have you been exposed to someone with 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 (082f674fce1dc942)', Time: '2021-01-17T07:09:15', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '5b29206a-e3c6-4411-951f-71798a90d911'	System	17 Jan 2021 13:09:21
User entered 'No (N)'	System	17 Jan 2021 13:09:21

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2021-01-17T07:09:18', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '5b29206a-e3c6-4411-951f-71798a90d911'	System	17 Jan 2021 13:09:21
User entered '17 Jan 2021 07:09:18'	System	17 Jan 2021 13:09:21

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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 (082f674fce1dc942)', Time: '2021-01-24T00:02:08', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'd29f62af-999b-4068-ad70-cccec7f88ac6'	System	24 Jan 2021 06:02:37
User entered 'No (N)'	System	24 Jan 2021 06:02:37

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

Have you been exposed to someone with 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 (082f674fce1dc942)', Time: '2021-01-24T00:02:10', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'd29f62af-999b-4068-ad70-cccec7f88ac6'	System	24 Jan 2021 06:02:37
User entered 'No (N)'	System	24 Jan 2021 06:02:37

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2021-01-24T00:02:18', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'd29f62af-999b-4068-ad70-cccec7f88ac6'	System	24 Jan 2021 06:02:37
User entered '24 Jan 2021 00:02:18'	System	24 Jan 2021 06:02:37

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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 (082f674fce1dc942)', Time: '2021-03-08T17:09:48', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'd3623a8a-839d-4ef1-bbee-5056142fa9c4'	System	08 Mar 2021 23:16:15
User entered 'No (N)'	System	08 Mar 2021 23:16:15

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

Have you been exposed to someone with 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 (082f674fce1dc942)', Time: '2021-03-08T17:09:59', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'd3623a8a-839d-4ef1-bbee-5056142fa9c4'	System	08 Mar 2021 23:16:15
User entered 'No (N)'	System	08 Mar 2021 23:16:15

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2021-03-08T17:10:09', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'd3623a8a-839d-4ef1-bbee-5056142fa9c4'	System	08 Mar 2021 23:16:15
User entered '08 Mar 2021 17:10:09'	System	08 Mar 2021 23:16:15

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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 (082f674fce1dc942)', Time: '2021-03-15T22:33:40', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ebf7a37b-4a77-4b14-a7a4-3027756878d5'	System	16 Mar 2021 03:34:03
User entered 'No (N)'	System	16 Mar 2021 03:34:03

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

Have you been exposed to someone with 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 (082f674fce1dc942)', Time: '2021-03-15T22:33:44', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ebf7a37b-4a77-4b14-a7a4-3027756878d5'	System	16 Mar 2021 03:34:03
User entered 'Yes (Y)'	System	16 Mar 2021 03:34:03

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Please 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 (082f674fce1dc942)', Time: '2021-03-15T22:33:48', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ebf7a37b-4a77-4b14-a7a4-3027756878d5'	System	16 Mar 2021 03:34:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Mar 2021 03:34:03

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2021-03-15T22:33:52', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'ebf7a37b-4a77-4b14-a7a4-3027756878d5'	System	16 Mar 2021 03:34:03
User entered '15 Mar 2021 22:33:52'	System	16 Mar 2021 03:34:03

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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 (082f674fce1dc942)', Time: '2021-03-22T18:29:45', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'c58270e9-0038-4ce7-a8ba-b39fe48446d3'	System	22 Mar 2021 23:30:23
User entered 'No (N)'	System	22 Mar 2021 23:30:23

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

Have you been exposed to someone with 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 (082f674fce1dc942)', Time: '2021-03-22T18:30:09', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'c58270e9-0038-4ce7-a8ba-b39fe48446d3'	System	22 Mar 2021 23:30:23
User entered 'No (N)'	System	22 Mar 2021 23:30:23

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2021-03-22T18:30:20', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'c58270e9-0038-4ce7-a8ba-b39fe48446d3'	System	22 Mar 2021 23:30:23
User entered '22 Mar 2021 18:30:20'	System	22 Mar 2021 23:30:23

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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 (082f674fce1dc942)', Time: '2021-04-15T12:54:43', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '148664ec-38b9-4530-946d-40c7ebe9c05c'	System	15 Apr 2021 18:07:40
User entered 'No (N)'	System	15 Apr 2021 18:07:40

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

Have you been exposed to someone with 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 (082f674fce1dc942)', Time: '2021-04-15T12:54:48', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '148664ec-38b9-4530-946d-40c7ebe9c05c'	System	15 Apr 2021 18:07:40
User entered 'No (N)'	System	15 Apr 2021 18:07:40

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2021-04-15T12:54:56', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '148664ec-38b9-4530-946d-40c7ebe9c05c'	System	15 Apr 2021 18:07:40
User entered '15 Apr 2021 12:54:56'	System	15 Apr 2021 18:07:40

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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 (082f674fce1dc942)', Time: '2021-04-20T05:54:15-05:00', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '70603777-0ff3-463d-96a7-59a4786b0d59' User entered 'No (N)'	System	20 Apr 2021 10:54:26
	System	20 Apr 2021 10:54:26

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

Have you been exposed to someone with 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 (082f674fce1dc942)', Time: '2021-04-20T05:54:17-05:00', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '70603777-0ff3-463d-96a7-59a4786b0d59' User entered 'No (N)'	System	20 Apr 2021 10:54:26

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2021-04-20T05:54:21-05:00', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: '70603777-0ff3-463d-96a7-59a4786b0d59' User entered '20 Apr 2021 05:54:21'	System	20 Apr 2021 10:54:26
	System	20 Apr 2021 10:54:26

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[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 (082f674fce1dc942)', Time: '2021-04-27T22:38:30-05:00', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'bed6da49-b0f4-48f3-9384-3f9d95a0ce3e'	System	29 Apr 2021 04:28:33
User entered 'No (N)'	System	29 Apr 2021 04:28:33

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

Have you been exposed to someone with 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 (082f674fce1dc942)', Time: '2021-04-27T22:38:36-05:00', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'bed6da49-b0f4-48f3-9384-3f9d95a0ce3e'	System	29 Apr 2021 04:28:33
User entered 'No (N)'	System	29 Apr 2021 04:28:33

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2021-04-27T22:38:45-05:00', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'bed6da49-b0f4-48f3-9384-3f9d95a0ce3e'	System	29 Apr 2021 04:28:33
User entered '27 Apr 2021 22:38:45'	System	29 Apr 2021 04:28:33

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 01:06:07

US3442068

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:06:07
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 01:06:07

US3442068

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:40:54

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2021-03-08T17:10:21', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'feafc2d1-ed54-49a9-84ea-46e03477424d'	System	08 Mar 2021 23:16:36
User entered 'No (N)'	System	08 Mar 2021 23:16:36

US3442068

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:40:54

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:37:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (082f674fce1dc942)', Time: '2021-03-08T17:10:29', User OID: 'PatientReportedOutcome (US3442068)', ODM File OID: 'feafc2d1-ed54-49a9-84ea-46e03477424d'	System	08 Mar 2021 23:16:36
User entered '08 Mar 2021 17:10:29'	System	08 Mar 2021 23:16:36

US3442068

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
DataPoint Verified.		24 Feb 2021 16:02:09
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Nov 2020 15:21:14

US3442068

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
DataPoint Verified.		24 Feb 2021 16:02:09
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered '16 Nov 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Nov 2020 15:21:14

US3442068

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
DataPoint Verified.		24 Feb 2021 16:02:09
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Nov 2020 15:21:14

US3442068

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
DataPoint Verified.		24 Feb 2021 16:02:09
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	16 Nov 2020 15:21:14

US3442068

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
DataPoint Verified.		24 Feb 2021 16:02:12
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Nov 2020 15:21:29

US3442068

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:25:32
User entered 'I'	System	16 Nov 2020 15:21:29

US3442068

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:51
DataPoint Verified.		24 Feb 2021 16:03:33
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 23:52:00

US3442068

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:51
DataPoint Verified.		24 Feb 2021 16:03:33
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered '8 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 23:52:00

US3442068

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:51
DataPoint Verified.		24 Feb 2021 16:03:33
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 23:52:00

US3442068

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:51
DataPoint Verified.		24 Feb 2021 16:03:33
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 23:52:00

US3442068

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:51
DataPoint Verified.		24 Feb 2021 16:03:39
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	08 Dec 2020 23:52:05

US3442068

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:51
User entered '1'	System	08 Dec 2020 23:52:05

US3442068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:51
DataPoint Verified.		24 Feb 2021 16:07:37
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:37:30

US3442068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:51
DataPoint Verified.		24 Feb 2021 16:07:37
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered '18 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:37:30

US3442068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:51
DataPoint Verified.		24 Feb 2021 16:07:37
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:37:30

US3442068

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:51
DataPoint Verified.		24 Feb 2021 16:07:37
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:37:30

US3442068

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:51
DataPoint Verified.		24 Feb 2021 16:07:40
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:37:42

US3442068

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:51
User entered '1'	System	20 Jan 2021 01:37:42

US3442068

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:51
DataPoint Verified.		24 Feb 2021 16:07:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Feb 2021 00:38:04

US3442068

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:51
DataPoint Verified.		24 Feb 2021 16:07:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered '19 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Feb 2021 00:38:04

US3442068

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:51
DataPoint Verified.		24 Feb 2021 16:07:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Feb 2021 00:38:04

US3442068

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:51
DataPoint Verified.		24 Feb 2021 16:07:53
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	23 Feb 2021 00:38:04

US3442068

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:51
DataPoint Verified.		24 Feb 2021 16:07:56
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Feb 2021 00:38:13

US3442068

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:37:51
User entered '1'	System	23 Feb 2021 00:38:13

US3442068

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
DataPoint Verified.		06 Apr 2021 17:20:45
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Mar 2021 00:11:54

US3442068

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
DataPoint Verified.		06 Apr 2021 17:20:45
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
User entered '11 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Mar 2021 00:11:54

US3442068

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

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 07:22:46
DataPoint Verified.		06 Apr 2021 17:20:45
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
User entered 'Clinic (Clinic)'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Mar 2021 00:11:54

US3442068

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'VISIT4'	System	12 Mar 2021 00:11:54

US3442068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:21:21
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:00

US3442068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:21:21
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:00

US3442068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:21:21
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:00

US3442068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	30 Mar 2021 18:18:00

US3442068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:21:21
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:00

US3442068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:21:21
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:00

US3442068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:21:21
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:00

US3442068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:21:21
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:00

US3442068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	30 Mar 2021 18:18:00

US3442068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:21:21
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:00

US3442068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	30 Mar 2021 18:18:00

US3442068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:21:21
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:00

US3442068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	30 Mar 2021 18:18:00

US3442068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:21:21
User entered empty.	Tisha Davis (b) (4) (b) (4)	30 Mar 2021 18:18:00

US3442068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered empty.	System	30 Mar 2021 18:18:00

US3442068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46

US3442068

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46

US3442068

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
DataPoint Verified.		06 Apr 2021 17:21:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Mar 2021 00:12:01

US3442068

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
DataPoint Verified.		06 Apr 2021 17:21:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	12 Mar 2021 00:12:01

US3442068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
DataPoint Verified.		06 Apr 2021 17:21:38
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Mar 2021 00:12:24

US3442068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
DataPoint Verified.		06 Apr 2021 17:21:38
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
User entered '11 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Mar 2021 00:12:24

US3442068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
DataPoint Verified.		06 Apr 2021 17:21:38
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
User entered '09:33'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Mar 2021 00:12:24

US3442068

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered '11 Mar 2021 09:33'	System	12 Mar 2021 00:12:24

US3442068

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
DataPoint Verified.		06 Apr 2021 17:21:42
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Mar 2021 00:13:01

US3442068

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:22:46
User entered 'I'	System	12 Mar 2021 00:13:01

US3442068

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

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
DataPoint Verified.		24 Feb 2021 16:09:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:39:21

US3442068

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

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
DataPoint Verified.		24 Feb 2021 16:09:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered '18 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:39:21

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

[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 17:32:11
DataPoint Verified.		24 Feb 2021 16:09:58
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Clinic (Clinic)'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:39:21

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
User entered 'UNBLND_DECIDE'	System	23 Jan 2021 01:39:21

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:54

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
DataPoint Verified.		24 Feb 2021 16:10:29
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered '18 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:40:08

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:54

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 17:32:11
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:22:56

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:54

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
DataPoint Verified.		24 Feb 2021 16:10:29
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:40:08

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:54

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:22:56

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:54

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
DataPoint Verified.		24 Feb 2021 16:10:29
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered '18 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:40:08

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:54

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
DataPoint Verified.		24 Feb 2021 16:10:29
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:40:08

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:54

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
DataPoint Verified.		24 Feb 2021 16:10:29
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:40:08

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:54

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
DataPoint Verified.		24 Feb 2021 16:10:29
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:40:08

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:54

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
DataPoint Verified.		24 Feb 2021 16:10:29
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:40:08

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:54

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
User entered empty.	System	23 Jan 2021 01:40:08

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:40:54

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
User entered empty.	System	23 Jan 2021 01:40:08

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
DataPoint Verified.		24 Feb 2021 16:10:37
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:40:32

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
DataPoint Verified.		24 Feb 2021 16:10:37
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered '18 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:40:32

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
DataPoint Verified.		24 Feb 2021 16:10:37
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered '09:46'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:40:32

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
User entered '18 Jan 2021 09:46'	System	23 Jan 2021 01:40:32

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
DataPoint Verified.		24 Feb 2021 16:10:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:40:57

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
DataPoint Verified.		24 Feb 2021 16:10:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered '18 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:40:57

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
DataPoint Verified.		24 Feb 2021 16:10:42
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered '09:44'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:40:57

US3442068

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:54

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:32:11
User entered '18 Jan 2021 09:44'	System	23 Jan 2021 01:40:57

US3442068

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:40:54

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:20:46
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:47:21
DataPoint Un-verified.	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:49:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:49:13
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 19:49:07
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	02 Sep 2020 23:12:31

US3442068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:51:43
Reviewed for Safety.		20 Jan 2021 22:50:00
User entered		20 Jan 2021 22:49:48
'USA-US017-2021-mRNA-1273-P301000006'		
User entered 'New'		20 Jan 2021 22:49:48

US3442068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Subject had 2 diagnoses: Cervical spondylosis with radiculopathy & Cervicalgia. Please add both the diagnosis' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 04:30:20
Query 'Subject had 2 diagnoses: Cervical spondylosis with radiculopathy & Cervicalgia. Please add both the diagnosis' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	06 Apr 2021 20:45:40
User opened query 'Subject had 2 diagnoses: Cervical spondylosis with radiculopathy & Cervicalgia. Please add both the diagnosis' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 17:34:05
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:32:21
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
User closed query 'For coding purposes, CERVICAL REPLACEMENT AND FUSION is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from Coder).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:09:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Cervical spondylosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Mar 2021 11:37:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Mar 2021 11:37:03
Query 'For coding purposes, CERVICAL REPLACEMENT AND FUSION is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' answered with 'updated per query' (Site from Coder).	Tisha Davis (b) (4) (b) (4)	04 Mar 2021 19:44:39
Data point term sent to Coder	System	04 Mar 2021 19:44:38
DataPoint Un-verified.	Tisha Davis (b) (4) (b) (4)	04 Mar 2021 19:44:04
Coding entries removed.	Tisha Davis (b) (4) (b) (4)	04 Mar 2021 19:44:04
User entered 'Cervical spondylosis with radiculopathy' reason for change: Data Entry Error	Tisha Davis (b) (4) (b) (4)	04 Mar 2021 19:44:04
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 20:51:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Spinal disorder, LLT: Spinal disorder - version MedDRA\\23.0.	Coder Import (b) (4)	21 Jan 2021 15:58:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Jan 2021 15:58:03
User opened query 'For coding purposes, CERVICAL REPLACEMENT AND FUSION is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from Coder).	(b) (4), (b) (6)	21 Jan 2021 15:54:05
Data point term sent to Coder	System	20 Jan 2021 01:55:55
User entered 'cervical replacement and fusion'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

US3442068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:53:11
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

US3442068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:53:25
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:53:35
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 20:53:36
User entered '30 Dec 2020'	Oluwatosin Akingbala	20 Jan 2021 01:55:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:53:39
User entered empty.	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:53:41
User entered 'No (N)'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:53:42
User entered '30 Dec 2020'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4)	25 Jan 2021 20:53:44
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 20:53:44
	Oluwatosin Akingbala	20 Jan 2021 01:55:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:53:45
User entered 'Grade 3/Severe (Grade 3/Severe)'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:53:49
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	20 Jan 2021 18:59:22
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	20 Jan 2021 01:55:02
User entered 'Yes (Y)'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:53:51
User entered '0'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:53:52
User entered '0'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

US3442068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:13:33
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).		11 Feb 2021 16:33:43
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'patient stayed overnight in hospital' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 14:56:09
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 19:24:16
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 20:59:43
DataPoint Verified.		25 Jan 2021 20:53:55
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		20 Jan 2021 18:59:49
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		20 Jan 2021 18:59:49
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		20 Jan 2021 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	20 Jan 2021 18:59:22
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	20 Jan 2021 18:59:22
User entered '1' reason for change: Data Entry Error	Alma Guel (b) (4)	20 Jan 2021 18:59:22
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	20 Jan 2021 18:58:45
User entered '0'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:29:21
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:59:36
DataPoint Verified.		25 Jan 2021 20:53:59
User entered '30 Dec 2020' reason for change: Data Entry Error	Alma Guel (b) (4)	20 Jan 2021 18:58:45
User entered empty.	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:29:22
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
User closed query 'PV Query: The subject was still hospitalized after event ended, please clarify why hospitalization was prolonged for an additional day and reported additional events if appropriate.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:46
Query 'PV Query: The subject was still hospitalized after event ended, please clarify why hospitalization was prolonged for an additional day and reported additional events if appropriate.' answered with 'subject was kept overnight for observation purposes ' (Site from Safety).	Tisha Davis (b) (4) (b) (4)	04 Mar 2021 19:45:06
User opened query 'PV Query: The subject was still hospitalized after event ended, please clarify why hospitalization was prolonged for an additional day and reported additional events if appropriate.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 19:24:45
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 20:59:38
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 20:54:00
User entered '31 Dec 2020' reason for change: Data Entry Error	Alma Guel (b) (4)	20 Jan 2021 18:58:45
User entered empty.	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:29:26
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:59:40
DataPoint Verified.		25 Jan 2021 20:54:01
User entered 'No (N)' reason for change: Data Entry Error	Alma Guel (b) (4)	20 Jan 2021 18:59:49
User entered empty.	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:03
User entered empty.	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:05
User entered '0'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:06
User entered '0'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:08
User entered '0'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:10
User entered 'Not Related (NOT RELATED)'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:11
User entered 'Not Related (NOT RELATED)'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:36
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
User closed query 'PV Query: As the last dose of was given on 22 Sep 2020, please update the action taken with mRNA-1273 from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:55
Query 'PV Query: As the last dose of was given on 22 Sep 2020, please update the action taken with mRNA-1273 from none to not applicable.' answered with 'updated per query' (Site from Safety).	Tisha Davis (b) (4) (b) (4)	04 Mar 2021 19:45:18
DataPoint Un-verified.	Tisha Davis (b) (4) (b) (4)	04 Mar 2021 19:44:04
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Tisha Davis (b) (4) (b) (4)	04 Mar 2021 19:44:04
User opened query 'PV Query: As the last dose of was given on 22 Sep 2020, please update the action taken with mRNA-1273 from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 19:22:24
DataPoint Verified.		25 Jan 2021 20:54:13
User entered 'None (NONE)'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:18
User entered '0'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:19
User entered 'I'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:22
User entered 'I'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Form: Adverse Events (1)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:25
User entered empty.	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:35:40
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:59:19
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 16:55:10
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 16:55:03
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'records sent' (Site from Safety).	Tisha Davis (b) (4) (b) (4)	04 Mar 2021 20:20:54
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records sent' (Site from Safety).	Tisha Davis (b) (4) (b) (4)	04 Mar 2021 20:20:43
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'no covid testing was completed..' (Site from Safety).	Tisha Davis (b) (4) (b) (4)	04 Mar 2021 19:54:05

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Mar 2021 19:44:04
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	04 Mar 2021 19:44:04
DataPoint Un-verified.	Tisha Davis (b) (4)	04 Mar 2021 19:44:04
	(b) (4)	
User entered 'subject has suffered from 2 degenerative cervical disc for several years, this was previously documented as medical history. Surgery serves as treatment for this long time diagnosis.'	Tisha Davis (b) (4)	04 Mar 2021 19:44:04
	(b) (4)	
reason for change: Data Entry Error		
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 19:24:53
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 19:22:46
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 19:22:33
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 20:54:29
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Jan 2021 01:55:02
User entered empty.	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Jan 2021 01:55:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Jan 2021 01:55:02

US3442068

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:54

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Jan 2021 18:59:49

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:40:54

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:20:46
Query 'Per medical records, subject was prescribed with vitamin D3 & Empagliflozen meds. Please update those in edc and source' canceled (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 22:09:01
Query 'Acetaminophen & MethylPREDINSolone meds were prescribed to the subject per medical records however there is no entry in source and EDC. Please refer to medical records and update the field as applicable' canceled (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 22:09:00
User opened query 'Per medical records, subject was prescribed with vitamin D3 & Empagliflozen meds. Please update those in edc and source' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 17:56:26
User opened query 'Acetaminophen & MethylPREDINSolone meds were prescribed to the subject per medical records however there is no entry in source and EDC. Please refer to medical records and update the field as applicable' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 17:52:25
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:19:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 23:44:37

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 21:07:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 21:07:35
Data point term sent to Coder	System	26 Oct 2020 18:54:38
Coding entries removed.	(b) (4), (b) (6)	26 Oct 2020 18:54:24
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 19:51:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:21:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:21:40
Data point term sent to Coder	System	26 Aug 2020 23:45:58
User entered 'ibuprofen'	(b) (4), (b) (6)	26 Aug 2020 23:45:14

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:52:01
User entered 'No (N)'		26 Aug 2020 23:45:14

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User closed query 'Per DM CLR: Please update the indication to specify the location of OSTEOARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 06:51:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:08:10
Query 'Per DM CLR: Please update the indication to specify the location of OSTEOARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:54:29
DataPoint Un-verified.	(b) (4), (b) (6)	26 Oct 2020 18:54:24
User entered 'OSTEOARTHRITIS: neck, bilaterally shoulders and knees' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 18:54:24
User opened query 'Per DM CLR: Please update the indication to specify the location of OSTEOARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:48:06
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 19:52:06
User entered 'osteoarthritis'	(b) (4), (b) (6)	26 Aug 2020 23:45:14

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:53:03
User entered '400'		26 Aug 2020 23:45:14

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:53:10
User entered 'mg (mg)'		26 Aug 2020 23:45:14

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:53:45
User entered empty.		26 Aug 2020 23:45:14

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:53:47
User entered 'as needed (PRN)'		26 Aug 2020 23:45:14

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:53:49
User entered empty.		26 Aug 2020 23:45:14

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:54:29
User entered 'Oral (ORAL)'		26 Aug 2020 23:45:14

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:54:31
User entered empty.		26 Aug 2020 23:45:14

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:54:33
User entered 'un UNK 2019'		26 Aug 2020 23:45:14

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:54:36
User entered '0'		26 Aug 2020 23:45:14

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:54
DataPoint Verified.		13 Apr 2021 18:49:04
User closed query 'Per medical records, PCP advised to stop take the meds. Please check with the subject to update this field in both EDC & SOURCE' (Site from CRA).		13 Apr 2021 18:49:03
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
Signature has been broken.	(b) (4) John Villegas (b) (4)	09 Apr 2021 21:41:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) John Villegas (b) (4)	09 Apr 2021 21:41:27
Query 'Per medical records, PCP advised to stop take the meds. Please check with the subject to update this field in both EDC & SOURCE' answered with 'updated' (Site from CRA).	(b) (4) John Villegas (b) (4)	09 Apr 2021 21:41:05
User opened query 'Per medical records, PCP advised to stop take the meds. Please check with the subject to update this field in both EDC & SOURCE' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 17:53:11
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 17:52:37
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:54:41
User entered 'Yes (Y)'		26 Aug 2020 23:45:14

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:54
DataPoint Verified.		13 Apr 2021 18:49:05
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Un-verified.	(b) (4)	
	John Villegas (b) (4)	09 Apr 2021 21:41:27
	(b) (4)	
Signature has been broken.	John Villegas (b) (4)	09 Apr 2021 21:41:27
	(b) (4)	
User entered '23 Dec 2020' reason for change: Data Entry Error	John Villegas (b) (4)	09 Apr 2021 21:41:27
	(b) (4)	
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 19:54:43
User entered empty.		26 Aug 2020 23:45:14

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:54
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:54:48
User entered 'No (N)'		26 Aug 2020 23:45:14

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:54
User entered empty.	System	26 Aug 2020 23:45:14

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:54
User entered empty.	System	26 Aug 2020 23:45:14

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:36:54
User entered empty.	System	26 Aug 2020 23:45:14

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:55:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:44
Data point term sent to Coder User entered 'citalopram'	System (b) (4), (b) (6)	26 Aug 2020 23:47:01 26 Aug 2020 23:46:04

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:55:05
User entered 'No (N)'		26 Aug 2020 23:46:04

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:55:14
User entered 'depression/anxiety'		26 Aug 2020 23:46:04

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:55:20
User entered '20'		26 Aug 2020 23:46:04

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:55:22
User entered 'mg (mg)'		26 Aug 2020 23:46:04

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 19:55:23
User entered empty.		26 Aug 2020 23:46:04

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:55:24
User entered 'once daily (QD)'		26 Aug 2020 23:46:04

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 19:55:27
User entered empty.		26 Aug 2020 23:46:04

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:56:13
User entered 'Oral (ORAL)'		26 Aug 2020 23:46:04

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:56:15
User entered empty.		26 Aug 2020 23:46:04

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:54

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:56:19
User entered 'un UNK 2019'		26 Aug 2020 23:46:04

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:56:21
User entered '0'		26 Aug 2020 23:46:04

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:56:23
User entered 'Yes (Y)'		26 Aug 2020 23:46:04

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:56:25
User entered empty.		26 Aug 2020 23:46:04

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:56:27
User entered 'No (N)'		26 Aug 2020 23:46:04

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 23:46:04

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 23:46:04

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 23:46:04

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Nov 2020 01:17:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 01:17:15
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	26 Oct 2020 18:55:38 26 Oct 2020 18:54:46
DataPoint Verified.	(b) (4)	17 Sep 2020 19:56:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:21:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:21:44
Data point term sent to Coder User entered 'gabapentin'	System (b) (4), (b) (6)	26 Aug 2020 23:47:01 26 Aug 2020 23:46:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:56:41
User entered 'No (N)'		26 Aug 2020 23:46:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of NEUROPATHY (Sensory or Motor). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:55:33
Query 'Per DM CLR: Please update the indication to reflect the location/type of NEUROPATHY (Sensory or Motor). Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'done' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 23:08:28
User entered 'NEUROPATHY: left arm' reason for change: Data Entry Error		26 Oct 2020 18:54:51
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of NEUROPATHY (Sensory or Motor). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:54:46
User entered 'neuropathy'		26 Oct 2020 18:54:46
		29 Sep 2020 10:47:46
	(b) (4), (b) (6)	17 Sep 2020 19:56:43
		26 Aug 2020 23:46:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:56:46
User entered '300'		26 Aug 2020 23:46:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 19:56:48
User entered 'mg (mg)'		26 Aug 2020 23:46:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:56:49
User entered empty.		26 Aug 2020 23:46:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:56:52
User entered 'once daily (QD)'		26 Aug 2020 23:46:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	17 Sep 2020 19:56:57
User entered empty.		26 Aug 2020 23:46:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:56:58
User entered 'Oral (ORAL)'		26 Aug 2020 23:46:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:57:00
User entered empty.		26 Aug 2020 23:46:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:57:02
User entered 'un UNK 2019'		26 Aug 2020 23:46:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:57:03
User entered '0'		26 Aug 2020 23:46:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:57:06
User entered 'Yes (Y)'		26 Aug 2020 23:46:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:57:07
User entered empty.		26 Aug 2020 23:46:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:57:08
User entered 'No (N)'		26 Aug 2020 23:46:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 23:46:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 23:46:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 23:46:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:57:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:44
Data point term sent to Coder User entered 'atorvastatin'	System (b) (4), (b) (6)	26 Aug 2020 23:48:04 26 Aug 2020 23:48:03

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:57:37
User entered 'No (N)'		26 Aug 2020 23:48:03

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:57:42
User entered 'hypercholesterolemia'		26 Aug 2020 23:48:03

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:57:44
User entered '10'		26 Aug 2020 23:48:03

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:57:45
User entered 'mg (mg)'		26 Aug 2020 23:48:03

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:57:48
User entered empty.		26 Aug 2020 23:48:03

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:57:50
User entered 'once daily (QD)'		26 Aug 2020 23:48:03

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:57:52
User entered empty.		26 Aug 2020 23:48:03

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:57:54
User entered 'Oral (ORAL)'		26 Aug 2020 23:48:03

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4)	17 Sep 2020 19:57:55
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 23:48:03

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:57:58
User entered 'UN UNK 2015'		26 Aug 2020 23:48:03

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 19:57:59
User entered '0'		26 Aug 2020 23:48:03

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:58:02
User entered 'Yes (Y)'		26 Aug 2020 23:48:03

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:58:04
User entered empty.		26 Aug 2020 23:48:03

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 19:58:08
User entered 'No (N)'		26 Aug 2020 23:48:03

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 23:48:03

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 23:48:03

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 23:48:03

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:58:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:44
Data point term sent to Coder User entered 'FENOFIBRATE'	System (b) (4), (b) (6)	26 Aug 2020 23:49:07 26 Aug 2020 23:48:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:58:29
User entered 'No (N)'		26 Aug 2020 23:48:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:58:32
User entered 'HYPERCHOLESTEROLEMIA'		26 Aug 2020 23:48:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:58:36
User entered '2.5'		26 Aug 2020 23:48:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 19:58:38
User entered 'mg (mg)'		26 Aug 2020 23:48:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:58:50
User entered empty.		26 Aug 2020 23:48:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 19:58:52
User entered 'once daily (QD)'		26 Aug 2020 23:48:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:58:55
User entered empty.		26 Aug 2020 23:48:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:59:00
User entered 'Oral (ORAL)'		26 Aug 2020 23:48:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 19:59:02
User entered empty.		26 Aug 2020 23:48:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:59:07
User entered 'UN UNK 2019'		26 Aug 2020 23:48:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 19:59:10
User entered '0'		26 Aug 2020 23:48:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:59:13
User entered 'Yes (Y)'		26 Aug 2020 23:48:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:59:15
User entered empty.		26 Aug 2020 23:48:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:59:19
User entered 'No (N)'		26 Aug 2020 23:48:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 23:48:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 23:48:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 23:48:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:59:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:49
Data point term sent to Coder User entered 'HYDROCHLORATHIAZIDE'	System (b) (4), (b) (6)	26 Aug 2020 23:50:08 26 Aug 2020 23:49:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:59:52
User entered 'No (N)'		26 Aug 2020 23:49:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 19:59:56
User entered 'HYPERTENSION'		26 Aug 2020 23:49:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:59:58
User entered '25'		26 Aug 2020 23:49:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:00:00
User entered 'mg (mg)'		26 Aug 2020 23:49:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:00:02
User entered empty.		26 Aug 2020 23:49:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:00:05
User entered 'once daily (QD)'		26 Aug 2020 23:49:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:00:06
User entered empty.		26 Aug 2020 23:49:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:00:08
User entered 'Oral (ORAL)'		26 Aug 2020 23:49:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:00:09
User entered empty.		26 Aug 2020 23:49:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:00:14
User entered 'UN UNK 2019'		26 Aug 2020 23:49:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 20:00:16
User entered '0'		26 Aug 2020 23:49:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:00:19
User entered 'Yes (Y)'		26 Aug 2020 23:49:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 20:00:20
User entered empty.		26 Aug 2020 23:49:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:00:23
User entered 'No (N)'		26 Aug 2020 23:49:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 23:49:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 23:49:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 23:49:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:00:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:49
Data point term sent to Coder	System	26 Aug 2020 23:51:10
User entered 'METFORMIN'	(b) (4), (b) (6)	26 Aug 2020 23:50:21

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:00:51
User entered 'No (N)'		26 Aug 2020 23:50:21

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:00:53
User entered 'TYPE 2 DIABETES'		26 Aug 2020 23:50:21

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:00:55
User entered '850'		26 Aug 2020 23:50:21

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:01:30
User entered 'mg (mg)'		26 Aug 2020 23:50:21

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:01:33
User entered empty.		26 Aug 2020 23:50:21

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:01:35
User entered 'twice daily (BID)'		26 Aug 2020 23:50:21

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4)	17 Sep 2020 20:01:36
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 23:50:21

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:01:38
User entered 'Oral (ORAL)'		26 Aug 2020 23:50:21

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:01:40
User entered empty.		26 Aug 2020 23:50:21

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 20:01:43
User entered 'UN UNK 2019'		26 Aug 2020 23:50:21

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:01:45
User entered '0'		26 Aug 2020 23:50:21

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:01:51
User entered 'Yes (Y)'		26 Aug 2020 23:50:21

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:01:53
User entered empty.		26 Aug 2020 23:50:21

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:01:58
User entered 'No (N)'		26 Aug 2020 23:50:21

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Aug 2020 23:50:21

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 23:50:21

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 23:50:21

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:02:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:49
Data point term sent to Coder User entered 'TOPIRAMATE'	System (b) (4), (b) (6)	26 Aug 2020 23:51:09 26 Aug 2020 23:51:00

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 20:02:16
User entered 'No (N)'		26 Aug 2020 23:51:00

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:02:23
User entered 'MIGRAINES'		26 Aug 2020 23:51:00

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:02:28
User entered '100'		26 Aug 2020 23:51:00

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:02:31
User entered 'mg (mg)'		26 Aug 2020 23:51:00

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:02:33
User entered empty.		26 Aug 2020 23:51:00

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:02:36
User entered 'once daily (QD)'		26 Aug 2020 23:51:00

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:02:38
User entered empty.		26 Aug 2020 23:51:00

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:02:40
User entered 'Oral (ORAL)'		26 Aug 2020 23:51:00

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:02:42
User entered empty.		26 Aug 2020 23:51:00

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 20:02:44
User entered 'UN UNK 2019'		26 Aug 2020 23:51:00

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:02:46
User entered '0'		26 Aug 2020 23:51:00

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:02:49
User entered 'Yes (Y)'		26 Aug 2020 23:51:00

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:02:52
User entered empty.		26 Aug 2020 23:51:00

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:02:55
User entered 'No (N)'		26 Aug 2020 23:51:00

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 23:51:00

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 23:51:00

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 23:51:00

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:04:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:51
Data point term sent to Coder User entered 'SUMATRIPTAN'	System (b) (4), (b) (6)	26 Aug 2020 23:52:12 26 Aug 2020 23:51:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 20:04:34
User entered 'No (N)'		26 Aug 2020 23:51:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:04:37
User entered 'MIGRAINES'		26 Aug 2020 23:51:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 20:04:40
User entered '50'		26 Aug 2020 23:51:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:04:43
User entered 'mg (mg)'		26 Aug 2020 23:51:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 20:04:44
User entered empty.		26 Aug 2020 23:51:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:04:53
User entered 'as needed (PRN)'		26 Aug 2020 23:51:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 20:05:01
User entered empty.		26 Aug 2020 23:51:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:05:02
User entered 'Oral (ORAL)'		26 Aug 2020 23:51:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:05:04
User entered empty.		26 Aug 2020 23:51:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:05:06
User entered 'UN UNK 2019'		26 Aug 2020 23:51:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:05:08
User entered '0'		26 Aug 2020 23:51:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:05:12
User entered 'Yes (Y)'		26 Aug 2020 23:51:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:05:14
User entered empty.		26 Aug 2020 23:51:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:05:18
User entered 'No (N)'		26 Aug 2020 23:51:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 23:51:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 23:51:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 23:51:39

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:05:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:21:52
Data point term sent to Coder	System	26 Aug 2020 23:53:12
User entered 'PANTOPRAZOLE'	(b) (4), (b) (6)	26 Aug 2020 23:52:23

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:05:43
User entered 'No (N)'		26 Aug 2020 23:52:23

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:05:49
User entered 'ACID REFLUX'		26 Aug 2020 23:52:23

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:05:51
User entered '40'		26 Aug 2020 23:52:23

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:05:53
User entered 'mg (mg)'		26 Aug 2020 23:52:23

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:05:55
User entered empty.		26 Aug 2020 23:52:23

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:05:59
User entered 'as needed (PRN)'		26 Aug 2020 23:52:23

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Sep 2020 20:06:00
User entered empty.		26 Aug 2020 23:52:23

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:06:02
User entered 'Oral (ORAL)'		26 Aug 2020 23:52:23

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:06:06
User entered empty.		26 Aug 2020 23:52:23

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:06:05
User entered 'un UNK 2019'		26 Aug 2020 23:52:23

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:06:09
User entered '0'		26 Aug 2020 23:52:23

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:41
User closed query 'Doesn't match with source. Please update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 23:09:20
Query 'Doesn't match with source. Please update accordingly. ' answered with 'source updated' (Site from CRA).		17 Sep 2020 23:30:15
User opened query 'Doesn't match with source. Please update accordingly. ' (Site from CRA).		17 Sep 2020 20:06:53
DataPoint Un-verified.		17 Sep 2020 20:06:22
DataPoint Verified.		17 Sep 2020 20:06:11
User entered 'Yes (Y)'		26 Aug 2020 23:52:23

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4)	10 Nov 2020 23:09:43
DataPoint Un-verified.	(b) (4), (b) (6)	17 Sep 2020 20:06:24
DataPoint Verified.		17 Sep 2020 20:06:13
User entered empty.		26 Aug 2020 23:52:23

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:06:15
User entered 'No (N)'		26 Aug 2020 23:52:23

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 23:52:23

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 23:52:23

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 23:52:23

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:54

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:17:08
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 08:00:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 08:00:05
Data point term sent to Coder	System	20 Jan 2021 01:49:53
User entered 'cyclobenzaprine'	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:48:59

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:17:08
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:48:59

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:17:08
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'cervical replacement and fusion'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:48:59

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 22:06:07
User closed query 'Per medical records, subject was advised to take 10mg. Please update the field as applicable.' (Site from CRA).		06 Apr 2021 22:06:04
Query 'Per medical records, subject was advised to take 10mg. Please update the field as applicable.' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	06 Apr 2021 20:50:12
DataPoint Un-verified.	Alma Guel (b) (4)	06 Apr 2021 20:50:02
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 20:50:02
User entered '10' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:50:02
User opened query 'Per medical records, subject was advised to take 10mg. Please update the field as applicable.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 17:53:55
DataPoint Verified.		24 Feb 2021 16:17:08
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered '5'	(b) (4)	
	Oluwatosin Akingbala	20 Jan 2021 01:48:59
	(b) (4)	

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:17:08
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'mg (mg)'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:48:59

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:54

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:17:08
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:48:59

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:06:09
DataPoint Un-verified.	Alma Guel (b) (4)	06 Apr 2021 20:50:02
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 20:50:02
User entered 'other (OTHER)' reason for change:	Alma Guel (b) (4)	06 Apr 2021 20:50:02
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:17:08
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'three times daily (TID)'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:48:59

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:06:10
DataPoint Un-verified.	Alma Guel (b) (4)	06 Apr 2021 20:50:02
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 20:50:02
User entered 'every 8 hours' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:50:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:17:08
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:48:59

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:17:08
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Oral (ORAL)'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:48:59

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:54

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:17:08
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:48:59

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:17:08
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered '30 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:48:59

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:17:08
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:48:59

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:17:08
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:48:59

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding ConProc. Please review and reconcile ConMed and ConProc start/stop dates as appropriate or provide explanation for why Con Med continued after the ConProc had resolved. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 07:39:25
Query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding ConProc. Please review and reconcile ConMed and ConProc start/stop dates as appropriate or provide explanation for why Con Med continued after the ConProc had resolved. ' answered with 'Per medical records subject was advised to continue per ordering physician ' (Site from DM).	John Villegas (b) (4) (b) (4)	09 Apr 2021 21:35:51
User opened query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding ConProc. Please review and reconcile ConMed and ConProc start/stop dates as appropriate or provide explanation for why Con Med continued after the ConProc had resolved. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 00:56:32
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:17:08
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Feb 2021 18:54:45
User entered empty.	Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:48:59

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:17:08
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:48:59

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:50:02
User entered '3'	System	20 Jan 2021 01:48:59

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:50:02
User entered '1'	System	20 Jan 2021 01:48:59

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:50:02
User entered '804 (804)'	System	20 Jan 2021 01:48:59

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;CODEINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Apr 2021 06:27:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 06:27:33
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:08:03
Data point term sent to Coder	System	06 Apr 2021 20:54:00
User entered 'acetaminophen-codeine'	Alma Guel (b) (4)	06 Apr 2021 20:53:43

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:04
User entered 'No (N)'	Alma Guel (b) (4)	06 Apr 2021 20:53:43

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:05
User entered 'appendicitis'	Alma Guel (b) (4)	06 Apr 2021 20:53:43

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:06
User entered '300/30'	Alma Guel (b) (4)	06 Apr 2021 20:53:43

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:08
User entered 'mg (mg)'	Alma Guel (b) (4)	06 Apr 2021 20:53:43

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:09
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:53:43

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:10
User entered 'other (OTHER)'	Alma Guel (b) (4)	06 Apr 2021 20:53:43

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:11
User entered 'every 4 hours'	Alma Guel (b) (4)	06 Apr 2021 20:53:43

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:12
User entered 'Oral (ORAL)'	Alma Guel (b) (4)	06 Apr 2021 20:53:43

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:14
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:53:43

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:16
User entered '30 Dec 2020'	Alma Guel (b) (4)	06 Apr 2021 20:53:43

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:54

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:17
User entered '0'	Alma Guel (b) (4)	06 Apr 2021 20:53:43

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:19
User entered 'Yes (Y)'	Alma Guel (b) (4)	06 Apr 2021 20:53:43

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:20
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:53:43

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:08:21
User entered 'No (N)'	Alma Guel (b) (4)	06 Apr 2021 20:53:43

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:53:43

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:53:43

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:53:43

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Apr 2021 08:30:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:30:03
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:07:41
Data point term sent to Coder	System	06 Apr 2021 20:55:00
User entered 'methylprednisolone'	Alma Guel (b) (4)	06 Apr 2021 20:54:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:42
User entered 'No (N)'	Alma Guel (b) (4)	06 Apr 2021 20:54:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:44
User entered 'appendicitis'	Alma Guel (b) (4)	06 Apr 2021 20:54:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:45
User entered '4'	Alma Guel (b) (4)	06 Apr 2021 20:54:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:46
User entered 'mg (mg)'	Alma Guel (b) (4)	06 Apr 2021 20:54:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:48
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:54:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:49
User entered 'once daily (QD)'	Alma Guel (b) (4)	06 Apr 2021 20:54:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:50
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:54:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:52
User entered 'Oral (ORAL)'	Alma Guel (b) (4)	06 Apr 2021 20:54:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:53
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:54:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:54
User entered '30 Dec 2020'	Alma Guel (b) (4)	06 Apr 2021 20:54:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:55
User entered '0'	Alma Guel (b) (4)	06 Apr 2021 20:54:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:57
User entered 'Yes (Y)'	Alma Guel (b) (4)	06 Apr 2021 20:54:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:58
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:54:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:59
User entered 'No (N)'	Alma Guel (b) (4)	06 Apr 2021 20:54:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 20:54:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 20:54:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Apr 2021 20:54:56

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 22:06:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 21:03:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	06 Apr 2021 21:02:06
User entered 'jardiance'	Alma Guel (b) (4)	06 Apr 2021 21:01:32

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:00
User entered 'No (N)'	Alma Guel (b) (4)	06 Apr 2021 21:01:32

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:01
User entered 'type 2 diabetes'	Alma Guel (b) (4)	06 Apr 2021 21:01:32

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:08
User entered '10'	Alma Guel (b) (4)	06 Apr 2021 21:01:32

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:09
User entered 'mg (mg)'	Alma Guel (b) (4)	06 Apr 2021 21:01:32

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:10
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:01:32

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:11
User entered 'once daily (QD)'	Alma Guel (b) (4)	06 Apr 2021 21:01:32

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:13
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:01:32

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:14
User entered 'Oral (ORAL)'	Alma Guel (b) (4)	06 Apr 2021 21:01:32

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:16
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:01:32

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:49:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	09 Apr 2021 21:39:33
User entered 'un UNK 2015' reason for change: Data Entry Error	John Villegas (b) (4)	09 Apr 2021 21:39:33
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	06 Apr 2021 21:01:32
User entered empty.	System	06 Apr 2021 21:01:32
	Alma Guel (b) (4)	06 Apr 2021 21:01:32

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:49:54
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
User entered '0'	(b) (4) Alma Guel (b) (4)	06 Apr 2021 21:01:32

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:50:02
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 21:39:33
User entered 'Yes (Y)' reason for change: Data Entry Error	John Villegas (b) (4)	09 Apr 2021 21:39:33
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	06 Apr 2021 21:01:32
	Alma Guel (b) (4)	06 Apr 2021 21:01:32

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:50:03
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
User entered empty.	(b) (4) Alma Guel (b) (4)	06 Apr 2021 21:01:32

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:18
User entered 'No (N)'	Alma Guel (b) (4)	06 Apr 2021 21:01:32

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 21:01:32

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 21:01:32

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Apr 2021 21:01:32

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:22
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: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D 3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:04:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 21:04:28
Data point term sent to Coder	System	06 Apr 2021 21:03:06
User entered 'Vitamin D 3'	Alma Guel (b) (4)	06 Apr 2021 21:02:52

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:24
User entered 'Yes (Y)'	Alma Guel (b) (4)	06 Apr 2021 21:02:52

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:25
User entered 'supplement'	Alma Guel (b) (4)	06 Apr 2021 21:02:52

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:26
User entered '2000'	Alma Guel (b) (4)	06 Apr 2021 21:02:52

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:28
User entered 'IU (IU)'	Alma Guel (b) (4)	06 Apr 2021 21:02:52

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:29
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:02:52

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:30
User entered 'twice daily (BID)'	Alma Guel (b) (4)	06 Apr 2021 21:02:52

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:32
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:02:52

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:33
User entered 'Oral (ORAL)'	Alma Guel (b) (4)	06 Apr 2021 21:02:52

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:07:34
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 21:02:52

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:49:37
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	09 Apr 2021 21:42:57
User entered 'un UNK 2019' reason for change: Data Entry Error	John Villegas (b) (4)	09 Apr 2021 21:42:57
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	06 Apr 2021 21:02:52
User entered empty.	System	06 Apr 2021 21:02:52
	Alma Guel (b) (4)	06 Apr 2021 21:02:52

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:49:38
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
User entered '0'	(b) (4) Alma Guel (b) (4)	06 Apr 2021 21:02:52

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:49:40
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 21:42:57
User entered 'Yes (Y)' reason for change: Data Entry Error	John Villegas (b) (4)	09 Apr 2021 21:42:57
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	06 Apr 2021 21:02:52
	Alma Guel (b) (4)	06 Apr 2021 21:02:52

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:49:41
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
User entered empty.	(b) (4) Alma Guel (b) (4)	06 Apr 2021 21:02:52

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:49:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 21:43:09
User entered 'No (N)' reason for change: Data Entry Error	John Villegas (b) (4)	09 Apr 2021 21:43:09
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	06 Apr 2021 21:02:52
	Alma Guel (b) (4)	06 Apr 2021 21:02:52

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Apr 2021 21:02:52

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 21:02:52

US3442068

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:40:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Apr 2021 21:02:52

US3442068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:40:54

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:20:46
DataPoint Verified.		24 Feb 2021 16:14:19
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Un-verified.	(b) (4)	
	Oluwatosin Akingbala	20 Jan 2021 01:39:11
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Oluwatosin Akingbala	20 Jan 2021 01:39:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 20:07:57
User entered 'No (N)'	Melody Dufrene (b) (4)	02 Sep 2020 23:12:38
	(b) (4)	

US3442068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:40:54

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 16:15:08
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered '30 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:43:35

US3442068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:40:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:08:49
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'cervical replacement and fusion two degenerative cervical disc'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:43:35

US3442068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:40:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:08:49
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered 'Adverse Event (AE)'	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:43:35

US3442068

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:40:54

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:08:49
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	20 Jan 2021 01:43:35

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:38
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'USA-US017-2021-MRNA-1273-P301000006'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:40
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'Yes (Y)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4)	25 Jan 2021 20:55:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 22:50:47
User entered 'No (N)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'No (N)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'Yes (Y)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'No (N)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'No (N)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'No (N)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'William'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'Seeger'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE-USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
User closed query 'Please correct the street number.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:09:17
DataPoint Verified.		06 Apr 2021 22:09:14
Query 'Please correct the street number.' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	06 Apr 2021 20:45:19
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Apr 2021 20:45:12
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 20:45:12
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:45:12
User opened query 'Please correct the street number.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 17:39:30
DataPoint Un-verified.		06 Apr 2021 17:39:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered '4505 Boat Club Road, Suite 400A'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'Fort Worth'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:09:14
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:45:12

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered '76135'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
User entered 'US'	System	20 Jan 2021 22:51:12

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Mar 2021 17:59:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
	(b) (4)	
User entered '1'	System	20 Jan 2021 22:51:12

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:38
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'USA-US017-2021-MRNA-1273-P301000006'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	25 Jan 2021 20:54:40
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'Yes (Y)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'No (N)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'No (N)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'Yes (Y)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'No (N)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'No (N)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'No (N)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'William'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'Seeger'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE-USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
User closed query 'Please correct the street number.' (Site from CRA).	(b) (4)	06 Apr 2021 22:09:17
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:14
Query 'Please correct the street number.' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	06 Apr 2021 20:45:19
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Apr 2021 20:45:12
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 20:45:12
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:45:12
User opened query 'Please correct the street number.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 17:39:30
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 17:39:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4)	25 Jan 2021 20:55:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 22:50:47
User entered '4505 Boat Club Road, Suite 400A'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'Fort Worth'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:09:14
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:45:12

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered '76135'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
User entered 'US'	System	20 Jan 2021 22:51:12

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Mar 2021 17:59:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
	(b) (4)	
User entered '1'	System	20 Jan 2021 22:51:12

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:40:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
User entered '20/Jan/2021 17:51'	System	20 Jan 2021 22:51:12

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:40:54

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.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
User entered 'I'		20 Jan 2021 22:51:12

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	25 Jan 2021 20:54:38
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'USA-US017-2021-MRNA-1273-P301000006'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:54:40
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'Yes (Y)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'No (N)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'No (N)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'Yes (Y)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'No (N)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'No (N)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'No (N)'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4)	25 Jan 2021 20:55:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 22:50:47
User entered 'William'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered 'Seeger'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
User closed query 'Please correct the street number.' (Site from CRA).	(b) (4)	06 Apr 2021 22:09:17
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:14
Query 'Please correct the street number.' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	06 Apr 2021 20:45:19
Un-reviewed for Safety.	Alma Guel (b) (4)	06 Apr 2021 20:45:12
Signature has been broken.	Alma Guel (b) (4)	06 Apr 2021 20:45:12
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Apr 2021 20:45:12
User opened query 'Please correct the street number.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 17:39:30
DataPoint Un-verified.		06 Apr 2021 17:39:17
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4)	25 Jan 2021 20:55:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 22:50:47
User entered '4505 Boat Club Road, Suite 400A'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4)	25 Jan 2021 20:55:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 22:50:47
User entered 'Fort Worth'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:19:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 22:09:14
User entered empty.	Alma Guel (b) (4)	06 Apr 2021 20:45:12

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	25 Jan 2021 20:55:00
Reviewed for Safety.		20 Jan 2021 22:50:47
User entered '76135'	System	20 Jan 2021 22:49:48

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 20:55:00
User entered 'US'	System	20 Jan 2021 22:51:12

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Mar 2021 17:59:55
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:54:45
	(b) (4)	
User entered '1'	System	20 Jan 2021 22:51:12

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:40:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
User entered '05/Mar/2021 12:59'	(b) (4) System	05 Mar 2021 17:59:55

US3442068

Folder: SAE USA-US017-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:40:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 22:09:14
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:32:25
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:59:55