

US3442024 (Prod: Benchmark Research - Fort Worth)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:42:11

All time stamps listed in this document are displayed in GMT

US3442024

Form: Participant Creation

Data signed: (b) (4) 13 Feb 2021 00:11:13

Generated On: 09 Jun 2021 17:42:11

[Participant ID](#)

US3442024

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

US3442024

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3442024

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Date of Informed Consent (<i>dd MMM yyyy</i>)	18 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

US3442024

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3442024

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 00:11:53

Generated On: 09 Jun 2021 17:42:11

Were any significant conditions reported?

Yes ☒
No ☐

US3442024

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3442024

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3442024

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Condition	HEARTBURN
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3442024

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 1956
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1956
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1956
Start Year (derived)	1956
Stop Month and Year (derived)	JAN 1956
Stop Year (derived)	1956

US3442024

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Condition	DIABETES MELLITUS
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3442024

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Condition	ERECTILE DYSFUNCTION
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)	_____

US3442024

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Condition	SLEEP APNEA
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)	_____

US3442024

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3442024

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Condition	PANIC ATTACKS
Start date (dd MMM yyyy)	UN UNK 1978
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 1978
Start Year (derived)	1978
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3442024

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Condition	INSOMNIA
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)	_____

US3442024

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Condition	POST TRAUMATIC STRESS DISORDER
Start date (dd MMM yyyy)	UN AUG 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)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3442024

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Condition	OSTEOARTHRITIS: BACK, RIGHT HIP, RIGHT KNEE
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)	

US3442024

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Condition	LUMBAR BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3442024

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1956
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1956
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1956
Start Year (derived)	1956
Stop Month and Year (derived)	JAN 1956
Stop Year (derived)	1956

US3442024

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:20 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 11:20
Height (<i>xxx.x</i>)	78.0 in
Weight (<i>xxx.x</i>)	265.0 lb
BMI (<i>xxx.x</i>)	30.68786 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)	

US3442024

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 AUG 2020

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

US3442024

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

RETIRED, SUBJECTS SPOUSE IS
A BUS DRIVER

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3442024

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

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	

US3442024

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

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

What was the participant's randomization number? 186809

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 ☒

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Height	ND - Not Done
Weight	ND - Not Done

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 AUG 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 11:20
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 AUG 2020
Time of assessment (00:00-23:59)	13:22 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 13:22
Temperature (xxx.x)	96.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3442024

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

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.

US3442024

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 18 AUG 2020

What was the treatment time? (00:00-23:59) 12:35 (24 HR)

Treatment Date and Time (derived) 18 AUG 2020 12:35

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

US3442024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 AUG 2020
Collection time (00:00-23:59)	11:50 (24 HR)
Collection date and time (derived)	18 AUG 2020 11:50

US3442024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Collection date (dd MMM yyyy)			18 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:56	18 AUG 2020 11:56
Nasopharyngeal Swab 2	No		

US3442024

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

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

96.4 °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

18 AUG 2020 13:23

PC Open Date & Time

18 AUG 2020 12:55

PC Close Date & Time

18 AUG 2020 15:25

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 17:48

PC Open Date & Time

18 AUG 2020 16:20

PC Close Date & Time

19 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:11

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

96.6 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

19 AUG 2020 16:42

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:11

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 16:52

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:11

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

97.9 °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

21 AUG 2020 15:50

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:11

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

22 AUG 2020 19:04

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:11

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

96.3 °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 AUG 2020 13:18

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:11

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

95.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 13:40

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 13:23

PC Open Date & Time

18 AUG 2020 12:55

PC Close Date & Time

18 AUG 2020 15:25

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 17:49

PC Open Date & Time

18 AUG 2020 16:20

PC Close Date & Time

19 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 16:42

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 16:53

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 15:50

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 19:04

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 13:18

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 13:40

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 13:24
PC Open Date & Time	18 AUG 2020 12:55
PC Close Date & Time	18 AUG 2020 15:25

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 17:49
PC Open Date & Time	18 AUG 2020 16:20
PC Close Date & Time	19 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

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 ☒

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 16:43
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2793

EAB) (1725)

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 16:53
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 2793

EAB) (1725)

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 15:50
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

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

64 of 2793

EAB) (1725)

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 19:05
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

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 ☒

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 13:18
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

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 ☒

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 13:41
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3442024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442024

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442024

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442024

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

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)	17 SEP 2020
Time of assessment (00:00-23:59)	09:36 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 09:36
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

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)	17 SEP 2020
Time of assessment (00:00-23:59)	10:53 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 10:53
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3442024

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3442024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

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) 17 SEP 2020

What was the treatment time? (00:00-23:59) 10:20 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 10:20

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

US3442024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 SEP 2020

Collection time (00:00-23:59)

09:46 (24 HR)

Collection date and time (derived)

17 SEP 2020 09:46

US3442024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:40	17 SEP 2020 09:40
Nasopharyngeal Swab 2	No		

US3442024

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

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

97.7 °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 17 SEP 2020 10:54

PC Open Date & Time 17 SEP 2020 10:40

PC Close Date & Time 17 SEP 2020 13:10

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

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	17 SEP 2020 15:56
PC Open Date & Time	17 SEP 2020 14:05
PC Close Date & Time	18 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:11

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

18 SEP 2020 12:32

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:11

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

97.8 °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

19 SEP 2020 18:51

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:11

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

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

20 SEP 2020 12:20

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

21 SEP 2020 15:13

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:11

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

97.7 °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

22 SEP 2020 15:49

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 23:26

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 10:55

PC Open Date & Time

17 SEP 2020 10:40

PC Close Date & Time

17 SEP 2020 13:10

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 15:56

PC Open Date & Time

17 SEP 2020 14:05

PC Close Date & Time

18 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 12:32

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 18:51

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 12:20

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:11

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

21 SEP 2020 15:14

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:11

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

22 SEP 2020 15:50

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:11

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

23 SEP 2020 23:27

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 10:55
PC Open Date & Time	17 SEP 2020 10:40
PC Close Date & Time	17 SEP 2020 13:10

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 15:57
PC Open Date & Time	17 SEP 2020 14:05
PC Close Date & Time	18 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

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 ☒

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:33
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

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 ☒

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 18:52
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

108 of 2793

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

110 of 2793

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 15:15
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

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 ☒

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 15:50
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

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 ☒

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 23:27
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3442024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442024

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442024

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:11:53

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442024

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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

US3442024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

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) _____

US3442024

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

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.

US3442024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 OCT 2020
Collection time (00:00-23:59)	09:34 (24 HR)
Collection date and time (derived)	16 OCT 2020 09:34

US3442024

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:11:15

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 04:44:12

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 09:47:38

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	14 DEC 2020 10:58:41
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	21 DEC 2020 16:16:15
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	24 DEC 2020 00:05:05
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

31 DEC 2020 12:39:17

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 00:03:06
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 00:32:31
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

21 JAN 2021 10:11:26

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 19:10:26

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 13:37:52

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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="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"/>

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

11 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 00:02:34

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 02:33:50

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 17:33:45

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 09:50:53

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 00:53:01

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 03:23:31

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

08 APR 2021 06:57:22

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

15 APR 2021 00:07:14

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

26 APR 2021 17:44:27

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 00:01:44

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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"/>

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 306

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

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

No ☐

Yes ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 320

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

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

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

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

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

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

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 348

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

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

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

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

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

Date and time of submission	
Patient Cloud Open Date & Time	29 JUL 2021 00:01
Patient Cloud Close Date & Time	02 AUG 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	12 AUG 2021 00:01
Patient Cloud Close Date & Time	16 AUG 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	19 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	23 AUG 2021 23:59
---	-------------------

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	06 SEP 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	27 SEP 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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"/>

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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"/>

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 467

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

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

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

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

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	13 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	03 FEB 2022 00:01
Patient Cloud Close Date & Time	07 FEB 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	10 FEB 2022 00:01
Patient Cloud Close Date & Time	14 FEB 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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="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"/>

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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"/>

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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"/>

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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"/>

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	14 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 705

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

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

No ☐

Yes ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 712

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

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

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

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

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

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

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	11 AUG 2022 00:01
Patient Cloud Close Date & Time	15 AUG 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

DAY 768

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

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

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

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

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

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

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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

Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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"/>

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	20 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3442024

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:42:11

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		15 MAR 2021 17:34:00

US3442024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:11:53

Generated On: 09 Jun 2021 17:42:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442024

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442024

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:11:53

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442024

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:51:35

Generated On: 09 Jun 2021 17:42:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442024

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:51:35

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

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

Visit date (dd MMM yyyy)	22 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
------------	--------

US3442024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

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) _____

US3442024

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

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.

US3442024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	22 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	13:41 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	22 MAR 2021 13:41
------------------------------------	-------------------

US3442024

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442024

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442024

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442024

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3442024

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:42:11

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"/>

US3442024

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:42:11

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3442024

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

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

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

Visit date (dd MMM yyyy)	14 JAN 2021
--------------------------	-------------

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
------------	---------------

US3442024

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

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:26:05

Generated On: 09 Jun 2021 17:42:11

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3442024

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Height	
Weight	
BMI (xxx.x)	

US3442024

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 10:15
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3442024

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 11:40
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3442024

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

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3442024

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

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 14 JAN 2021

What was the treatment time? (00:00-23:59) 11:06 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 11:06

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

US3442024

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

10:20 (24 HR)

Collection date and time (derived)

14 JAN 2021 10:20

US3442024

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	10:18
Collection Date and Time (derived)	14 JAN 2021 10:18

US3442024

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

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442024

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442024

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Mar 2021 21:26:05

Generated On: 09 Jun 2021 17:42:11

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 FEB 2021
Time of assessment (00:00-23:59)	13:07 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 13:07
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Mar 2021 21:26:05

Generated On: 09 Jun 2021 17:42:11

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	23 FEB 2021
Time of assessment (00:00-23:59)	14:20 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 14:20
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3442024

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:26:05

Generated On: 09 Jun 2021 17:42:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 FEB 2021

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

US3442024

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 18 Mar 2021 21:26:04

Generated On: 09 Jun 2021 17:42:11

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 23 FEB 2021

What was the treatment time? (00:00-23:59) 13:43 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 13:43

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

What was the frequency of the study treatment dosing? ONCE

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

US3442024

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:26:04

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442024

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:26:05

Generated On: 09 Jun 2021 17:42:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442024

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:26:05

Generated On: 09 Jun 2021 17:42:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442024

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3442024

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	22 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	13:33 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 13:33
Temperature (<i>xxx.x</i>)	99.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3442024

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

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.

US3442024

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 MAR 2021
Collection time (00:00-23:59)	13:41 (24 HR)
Collection date and time (derived)	22 MAR 2021 13:41

US3442024

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Feb 2021 00:11:13

Generated On: 09 Jun 2021 17:42:11

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Apr 2021 15:16:42

Generated On: 09 Jun 2021 17:42:11

AEID	USA-US017-2020-MRNA-1273-P30 1000007
Adverse event	WORSENING OF RIGHT HIP OSTEOARTHRITIS
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)	07 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)	08 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)	07 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	08 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	361 of 2793

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Apr 2021 15:16:42

Generated On: 09 Jun 2021 17:42:11

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	PATIENT HAS HAD OSTEOARTHRITIS IN RIGHT HIP SINCE 2015, PER PATIENT PCP, PATIENT HAD RIGHT HIP REPLACEMENT.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
PRODUCTION RELEASE (v12.003 EAB) (1725)	
362 of 2793	

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Apr 2021 15:16:42

Generated On: 09 Jun 2021 17:42:11

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

0

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Apr 2021 15:16:42

Generated On: 09 Jun 2021 17:42:11

AEID

Adverse event

PAIN RIGHT HIP (DUE TO
RIGHT HIP REPLACEMENT)

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

364 of 2793

EAB) (1725)

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Apr 2021 15:16:42

Generated On: 09 Jun 2021 17:42:11

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	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

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

Yes ☒

No ☐

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

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication	DETEMIR
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DM 2
Dose per administration	24
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input checked="" type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

367 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	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 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	07 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DM 2

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

369 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	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 1998
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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication EMPAGLIFLOZIN

Prophylaxis Yes ☐
No ☒

Indication DM 2

Dose per administration 12.5

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

371 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	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 2018	
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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication GLIZIPIDE

Prophylaxis Yes ☐
No ☒

Indication DM 2

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

EAB) (1725)

373 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	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 2012	
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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication PIOGLITAZONE

Prophylaxis Yes ☐
No ☒

Indication DM 2

Dose per administration 45

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

375 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

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

EAB) (1725)

377 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	07 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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

EAB) (1725)

379 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication NAPROXEN NA

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 440

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

381 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	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 FEB 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	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)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

385 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	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)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication FLUZONE QUADRIVALENT

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA

Dose per administration 0.7

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

387 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication PERCOCET

Prophylaxis Yes ☐
No ☒

Indication PAIN IN RIGHT HIP DUE TO HIP
REPLACEMENT SURGERY

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	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)	07 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication LACTATED RINGERS SOLUTION

Prophylaxis Yes ☒
No ☐

Indication IV DRIP FOR SURGERY

Dose per administration 1,000

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

CONTINUOUS
ADMINISTRATION

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	07 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication LIDOCAINE PF

Prophylaxis Yes ☒
No ☐

Indication PAIN DURING HIP SURGERY

Dose per administration 0.3

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

393 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRADERMAL	
Start date (dd MMM yyyy)	07 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	07 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication HYDROMORPHENE (DILAUDID)

Prophylaxis Yes ☒
No ☐

Indication PAIN DURING HIP SURGERY

Dose per administration 0.2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

395 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 07 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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication ASPIRIN ECOTRIN

Prophylaxis Yes ☒
No ☐

Indication DVT

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

397 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	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)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication SODIUM CHOLRIDE (NS FLUSH)

Prophylaxis Yes ☒
No ☐

Indication RIGHT HIP REPLACEMENT

Dose per administration 2

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

399 of 2793

EAB) (1725)

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 08 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication POLYETHYLENE GLYCOL

Prophylaxis Yes ☒
No ☐

Indication STOOL SOFTENER

Dose per administration 17

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

401 of 2793

EAB) (1725)

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	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)		07 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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication DIAZEPAM SOLUTION

Prophylaxis Yes ☒
No ☐

Indication IV DRIP FOR SURGERY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

403 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication FENTANYL SOLUTION

Prophylaxis Yes ☒
No ☐

Indication IV DRIP FOR SURGERY

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 ☐

PRODUCTION RELEASE (v12.003

405 of 2793

EAB) (1725)

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 07 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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication MORPHINE SOLUTION

Prophylaxis Yes ☒
No ☐

Indication IV DRIP SURGERY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

407 of 2793

EAB) (1725)

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication LIDOCAINE PF SOLUTION

Prophylaxis Yes ☒
No ☐

Indication IV DRIP FOR SURGERY

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 ☐

PRODUCTION RELEASE (v12.003

409 of 2793

EAB) (1725)

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 07 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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication PROPOFOL EMULSION

Prophylaxis Yes ☒
No ☐

Indication IV DRIP FOR SURGERY

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

EAB) (1725)

411 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 07 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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication ROCURONIUM SOLUTION

Prophylaxis Yes ☒
No ☐

Indication IV DRIP FOR SURGERY

Dose per administration 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

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

PRODUCTION RELEASE (v12.003

413 of 2793

EAB) (1725)

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 07 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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☒
No ☐

Indication IV DRIP FOR SURGERY

Dose per administration 8

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

415 of 2793

EAB) (1725)

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication FAMOTIDINE SOLUTION

Prophylaxis Yes ☒
No ☐

Indication IV DRIP FOR SURGERY

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

417 of 2793

EAB) (1725)

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication TRANEXAMIC ACID SOLUTION

Prophylaxis Yes ☒
No ☐

Indication IV DRIP FOR SURGERY

Dose per administration 1000

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

419 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication NEOSTIGMINE SOLUTION

Prophylaxis Yes ☒
No ☐

Indication IV DRIP FOR SURGERY

Dose per administration 3

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

421 of 2793

EAB) (1725)

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication GLYCOPYRROLATE SOLUTION

Prophylaxis Yes ☒
No ☐

Indication IV DRIP FOR SURGERY

Dose per administration 0.6

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

423 of 2793

EAB) (1725)

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 07 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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication ONDANSETRON SOLUTION

Prophylaxis Yes ☒
No ☐

Indication IV DRIP FOR SURGERY

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

425 of 2793

EAB) (1725)

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 07 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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication INSULIN DETEMIR

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES (DM II)

Dose per administration 27

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

427 of 2793

EAB) (1725)

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	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)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

429 of 2793

EAB) (1725)

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	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)		07 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"/>

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

Name of Medication LACTADED RINGERS
SOLUTION

Prophylaxis Yes ☒
No ☐

Indication IV DRIP FOR SURGERY

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

CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

431 of 2793

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 29 Apr 2021 23:22:54

Generated On: 09 Jun 2021 17:42:11

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	07 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 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"/>

US3442024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Feb 2021 00:11:14

Generated On: 09 Jun 2021 17:42:11

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3442024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 14 Apr 2021 20:45:52

Generated On: 09 Jun 2021 17:42:11

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
7 DEC 2020	TOTAL HIP ARTHROPLASTY ON THE RIGHT	Adverse Event	

US3442024

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:42:11

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

US3442024

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:42:11

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 ☐

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

SAEID	USA-US017-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

SAEID	USA-US017-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	15/DEC/2020 09:44
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

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

SAEID	USA-US017-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	29/JAN/2021 14:57
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

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

SAEID	USA-US017-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	29/JAN/2021 16:19
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

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

SAEID	USA-US017-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	01/MAR/2021 14:46
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

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 13 Apr 2021 15:16:43

Generated On: 09 Jun 2021 17:42:11

SAEID	USA-US017-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	24/MAR/2021 13:44
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

US3442024 (Prod: Benchmark Research - Fort Worth)

US3442024

Form: Participant Creation

Generated On: 09 Jun 2021 17:42:11

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'US3442024'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 16:09:43

US3442024

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 17:41:59

US3442024

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '18 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 16:09:44

US3442024

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[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 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Clinic (Clinic)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:41:59

US3442024

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'SCRN'	System	18 Aug 2020 17:41:59

US3442024

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:11

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered (b) (6) 1951'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 16:09:45

US3442024

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:11

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '69'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 17:42:28

US3442024

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:11

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'YEARS'	System	18 Aug 2020 17:42:28

US3442024

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '69'	System	18 Aug 2020 17:42:42

US3442024

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:11

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Male (M)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:42:28

US3442024

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:11

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:11:17
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 17:42:28

US3442024

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:11

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'I'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:42:28

US3442024

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:11

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 17:42:28

US3442024

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:11

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:42:28

US3442024

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:42:28

US3442024

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:42:28

US3442024

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 17:42:28

US3442024

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:11

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 17:42:28

US3442024

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:11

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 17:42:28

US3442024

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:42:11

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 17:42:28

US3442024

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:11

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '18 Aug 2020'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 17:42:42

US3442024

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Aug 2020'	System	18 Aug 2020 17:42:42

US3442024

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '2020'	System	18 Aug 2020 17:42:42

US3442024

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:11

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Amendment 2 (2)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:42:42

US3442024

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:42:42

US3442024

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:11

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 17:42:42

US3442024

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 17:42:42

US3442024

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:42:42

US3442024

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 16:09:44

US3442024

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:42:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '1'	System	18 Aug 2020 17:42:47

US3442024

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:42:47

US3442024

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:42:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:53
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:39:30

US3442024

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 22:58:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 22:58:29
Data point term sent to Coder	System	18 Aug 2020 18:40:45
User entered 'ALLERGIC RHINITIS'	Melody Dufrene (b) (4)	18 Aug 2020 18:40:16

US3442024

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN UNK 1970'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:40:16

US3442024

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:40:16

US3442024

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:40:16

US3442024

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:40:16

US3442024

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:40:16

US3442024

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Jan 1970'	System	18 Aug 2020 18:40:16

US3442024

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '1970'	System	18 Aug 2020 18:40:16

US3442024

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:40:16

US3442024

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:40:16

US3442024

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Aug 2020 23:06:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:06:33
Data point term sent to Coder	System	18 Aug 2020 18:41:48
User entered 'GERD'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:41:36

US3442024

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN UNK 1990'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:41:36

US3442024

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:41:36

US3442024

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:41:36

US3442024

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:41:36

US3442024

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:41:36

US3442024

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Jan 1990'	System	18 Aug 2020 18:41:36

US3442024

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '1990'	System	18 Aug 2020 18:41:36

US3442024

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:41:36

US3442024

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:41:36

US3442024

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:06:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:06:35
Data point term sent to Coder	System	18 Aug 2020 18:42:49
User entered 'HEARTBURN'	Melody Dufrene (b) (4)	18 Aug 2020 18:42:01

US3442024

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN UNK 1990'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:42:01

US3442024

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:42:01

US3442024

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:42:01

US3442024

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:42:01

US3442024

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:42:01

US3442024

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Jan 1990'	System	18 Aug 2020 18:42:01

US3442024

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '1990'	System	18 Aug 2020 18:42:01

US3442024

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:42:01

US3442024

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:42:01

US3442024

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:15:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:15:06
Data point term sent to Coder	System	18 Aug 2020 18:43:53
User entered 'TONSILLITIS'	Melody Dufrene (b) (4)	18 Aug 2020 18:43:35

US3442024

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN UNK 1956'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:43:35

US3442024

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:43:35

US3442024

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:43:35

US3442024

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN UNK 1956'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:43:35

US3442024

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:43:35

US3442024

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Jan 1956'	System	18 Aug 2020 18:43:35

US3442024

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '1956'	System	18 Aug 2020 18:43:35

US3442024

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Jan 1956'	System	18 Aug 2020 18:43:35

US3442024

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '1956'	System	18 Aug 2020 18:43:35

US3442024

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:19:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:19:06
Data point term sent to Coder	System	18 Aug 2020 18:44:54
User entered 'DIABETES MELLITUS'	Melody Dufrene (b) (4)	18 Aug 2020 18:44:16

US3442024

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN UNK 1998'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:44:16

US3442024

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:44:16

US3442024

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:44:16

US3442024

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:44:16

US3442024

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:44:16

US3442024

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Jan 1998'	System	18 Aug 2020 18:44:16

US3442024

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '1998'	System	18 Aug 2020 18:44:16

US3442024

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:44:16

US3442024

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:44:16

US3442024

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:19:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:19:07
Data point term sent to Coder	System	18 Aug 2020 18:44:57
User entered 'ERECTILE DYSFUNCTION'	Melody Dufrene (b) (4)	18 Aug 2020 18:44:40

US3442024

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN UNK 2010'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:44:40

US3442024

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:44:40

US3442024

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:44:40

US3442024

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:44:40

US3442024

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:44:40

US3442024

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Jan 2010'	System	18 Aug 2020 18:44:40

US3442024

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '2010'	System	18 Aug 2020 18:44:40

US3442024

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:44:40

US3442024

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:44:40

US3442024

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Aug 2020 23:23:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:23:12
Data point term sent to Coder	System	18 Aug 2020 18:46:00
User entered 'HYPERTENSION'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:45:15

US3442024

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN UNK 2005'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:45:15

US3442024

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:45:15

US3442024

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:45:15

US3442024

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:45:15

US3442024

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:45:15

US3442024

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Jan 2005'	System	18 Aug 2020 18:45:15

US3442024

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '2005'	System	18 Aug 2020 18:45:15

US3442024

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:45:15

US3442024

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:45:15

US3442024

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as SOC: Investigations, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:23:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:23:11
Data point term sent to Coder	System	18 Aug 2020 18:45:57
User entered 'HIGH CHOLESTEROL'	Melody Dufrene (b) (4)	18 Aug 2020 18:45:32

US3442024

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN UNK 2005'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:45:32

US3442024

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:45:32

US3442024

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:45:32

US3442024

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:45:32

US3442024

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:45:32

US3442024

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Jan 2005'	System	18 Aug 2020 18:45:32

US3442024

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '2005'	System	18 Aug 2020 18:45:32

US3442024

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:45:32

US3442024

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:45:32

US3442024

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Aug 2020 23:23:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:23:11
Data point term sent to Coder	System	18 Aug 2020 18:46:00
User entered 'SLEEP APNEA'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:45:55

US3442024

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN UNK 2012'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:45:55

US3442024

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:45:55

US3442024

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:45:55

US3442024

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:45:55

US3442024

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:45:55

US3442024

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Jan 2012'	System	18 Aug 2020 18:45:55

US3442024

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '2012'	System	18 Aug 2020 18:45:55

US3442024

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:45:55

US3442024

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:45:55

US3442024

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as SOC: Psychiatric disorders, HLGTT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:25:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:25:04
Data point term sent to Coder	System	18 Aug 2020 18:48:04
User entered 'MILD DEPRESSION'	Melody Dufrene (b) (4)	18 Aug 2020 18:47:14

US3442024

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN UNK 2000'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:47:14

US3442024

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:47:14

US3442024

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:47:14

US3442024

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:47:14

US3442024

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:47:14

US3442024

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Jan 2000'	System	18 Aug 2020 18:47:14

US3442024

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '2000'	System	18 Aug 2020 18:47:14

US3442024

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:47:14

US3442024

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:47:14

US3442024

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:25:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:25:04
Data point term sent to Coder	System	18 Aug 2020 18:48:05
User entered 'ANXIETY'	Melody Dufrene (b) (4)	18 Aug 2020 18:47:34

US3442024

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN UNK 1980'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:47:34

US3442024

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:47:34

US3442024

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:47:34

US3442024

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:47:34

US3442024

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:47:34

US3442024

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Jan 1980'	System	18 Aug 2020 18:47:34

US3442024

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '1980'	System	18 Aug 2020 18:47:34

US3442024

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:47:34

US3442024

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:47:34

US3442024

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Panic attacks and disorders, PT: Panic attack, LLT: Panic attacks - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:25:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:25:04
Data point term sent to Coder	System	18 Aug 2020 18:48:07
User entered 'PANIC ATTACKS'	Melody Dufrene (b) (4)	18 Aug 2020 18:47:59

US3442024

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN UNK 1978'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:47:59

US3442024

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:47:59

US3442024

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:47:59

US3442024

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:47:59

US3442024

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:47:59

US3442024

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Jan 1978'	System	18 Aug 2020 18:47:59

US3442024

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '1978'	System	18 Aug 2020 18:47:59

US3442024

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:47:59

US3442024

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:47:59

US3442024

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as SOC: Psychiatric disorders, HLTGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:25:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:25:07
Data point term sent to Coder	System	18 Aug 2020 18:49:10
User entered 'INSOMNIA'	Melody Dufrene (b) (4)	18 Aug 2020 18:48:21

US3442024

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN UNK 2012'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:48:21

US3442024

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:48:21

US3442024

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:48:21

US3442024

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:48:21

US3442024

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:48:21

US3442024

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Jan 2012'	System	18 Aug 2020 18:48:21

US3442024

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '2012'	System	18 Aug 2020 18:48:21

US3442024

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:48:21

US3442024

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:48:21

US3442024

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:25:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:25:07
Data point term sent to Coder	System	18 Aug 2020 18:49:13
User entered 'POST TRAUMATIC STRESS DISORDER'	Melody Dufrene (b) (4)	18 Aug 2020 18:49:01

US3442024

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN Aug 2019'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:49:01

US3442024

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:49:01

US3442024

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:49:01

US3442024

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:49:01

US3442024

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:49:01

US3442024

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Aug 2019'	System	18 Aug 2020 18:49:01

US3442024

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '2019'	System	18 Aug 2020 18:49:01

US3442024

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:49:01

US3442024

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:49:01

US3442024

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalised osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 14:06:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 14:06:54
Data point term sent to Coder	System	08 Oct 2020 19:51:03
Coding entries removed.	(b) (4), (b) (6)	08 Oct 2020 19:50:29
User entered 'OSTEOARTHRITIS: back, right hip, right knee' reason for change: Data Entry Error		08 Oct 2020 19:50:29
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)	18 Aug 2020 23:25:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:25:10
Data point term sent to Coder	System	18 Aug 2020 18:50:14
User entered 'OSTEOARTHRITIS'	Melody Dufrene (b) (4)	18 Aug 2020 18:49:28

US3442024

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN UNK 2015'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:49:28

US3442024

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:49:28

US3442024

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:49:28

US3442024

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:49:28

US3442024

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:49:28

US3442024

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Jan 2015'	System	18 Aug 2020 18:49:28

US3442024

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '2015'	System	18 Aug 2020 18:49:28

US3442024

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:49:28

US3442024

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:49:28

US3442024

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Lumbar pain - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:25:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:25:10
Data point term sent to Coder	System	18 Aug 2020 18:50:15
User entered 'LUMBAR BACK PAIN'	Melody Dufrene (b) (4)	18 Aug 2020 18:50:03

US3442024

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN UNK 2016'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:50:03

US3442024

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:50:03

US3442024

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:50:03

US3442024

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:50:03

US3442024

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:50:03

US3442024

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Jan 2016'	System	18 Aug 2020 18:50:03

US3442024

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '2016'	System	18 Aug 2020 18:50:03

US3442024

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:50:03

US3442024

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	18 Aug 2020 18:50:03

US3442024

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:25:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:25:18
Data point term sent to Coder	System	18 Aug 2020 18:52:18
User entered 'TONSILLECTOMY'	Melody Dufrene (b) (4)	18 Aug 2020 18:51:34

US3442024

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN UNK 1956'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:51:34

US3442024

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:51:34

US3442024

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:51:34

US3442024

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'UN UNK 1956'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:51:34

US3442024

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:51:34

US3442024

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Jan 1956'	System	18 Aug 2020 18:51:34

US3442024

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '1956'	System	18 Aug 2020 18:51:34

US3442024

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'Jan 1956'	System	18 Aug 2020 18:51:34

US3442024

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '1956'	System	18 Aug 2020 18:51:34

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:53:58

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '18 Aug 2020'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:53:58

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '11:20'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:53:58

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '18 Aug 2020 11:20'	System	18 Aug 2020 18:53:58

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '78.0' in	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:53:58
DataPoint set to visible.	(b) (4) System	18 Aug 2020 17:42:47

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '265.0' lb	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:53:58
DataPoint set to visible.	(b) (4) System	18 Aug 2020 17:42:47

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
Amendment Manager: User entered '30.68786'	System	17 Sep 2020 00:12:06
User entered '30.7'	System	18 Aug 2020 18:53:58
DataPoint set to visible.	System	18 Aug 2020 17:42:47

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'kg/m2'	System	18 Aug 2020 18:53:58
DataPoint set to visible.	System	18 Aug 2020 17:42:47

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:45:41
User entered '97.8' F	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:53:58

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:45:41
User entered 'Oral (Oral)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:53:58

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:53:58

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:45:41
User entered '74'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:53:58

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'bpm'	System	18 Aug 2020 18:53:58

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:45:41
User entered '16'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:53:58

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'breaths/min'	System	18 Aug 2020 18:53:58

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:45:41
User entered '124'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:53:58

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'mmHg'	System	18 Aug 2020 18:53:58

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:45:41
User entered '66'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:53:58

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'mmHg'	System	18 Aug 2020 18:53:58

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14

US3442024

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14

US3442024

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:54:14

US3442024

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '18 Aug 2020'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:54:14

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

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 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

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 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

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 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

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 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

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 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

[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 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

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 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

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 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

[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 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

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 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

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 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'RETIRED, SUBJECTS SPOUSE IS A BUS DRIVER'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

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 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

[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 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

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 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'I'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:42:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:56:05

US3442024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:40:34

US3442024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '18 Aug 2020'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:40:34

US3442024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[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 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Clinic (Clinic)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 17:40:34

US3442024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'VISIT1'	System	18 Aug 2020 17:40:34

US3442024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '18 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 17:10:08

US3442024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:11

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:18:35
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:18:35
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Aug 2020 17:10:08
User entered '186809' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 17:10:08

US3442024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:11

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 17:10:08

US3442024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:11

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 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 17:41:37

US3442024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:11

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 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 17:41:37

US3442024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:11

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 17:41:37

US3442024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:11

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Query 'Medical History and Con Meds doesn't match with the response. Please update the field accordingly. ' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 03:46:08
User opened query 'Medical History and Con Meds doesn't match with the response. Please update the field accordingly. ' (Site from CRA).		05 Oct 2020 03:44:14
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 17:41:37

US3442024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:11

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:41:37

US3442024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:11

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 21:03:01
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:34:45
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:17:59

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:46:49
User entered '78.0' in	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:46:49
User entered '265.0' lb	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:46:49
User entered '78.0' in	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:46:49
User entered '265.0' lb	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User accepted default value 'Pre-Dose (PREDOSE)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '18 Aug 2020'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '11:20'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered '18 Aug 2020 11:20'	System	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '97.8' F	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Oral (Oral)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '74'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'bpm'	System	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '16'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'breaths/min'	System	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '124'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'mmHg'	System	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '66'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'mmHg'	System	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:46:49
User entered '78.0' in	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:46:49
User entered '265.0' lb	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User accepted default value 'Post-Dose (POSTDOSE)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '18 Aug 2020'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:05:09
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 22:07:21
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		18 Aug 2020 18:59:43
User entered '13:22'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered '18 Aug 2020 13:22'	System	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User closed query 'CDM RQ: Please confirm if this result should be considered clinically significant or not.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 09:56:41
Query 'CDM RQ: Please confirm if this result should be considered clinically significant or not.' answered with 'Temp is correct as entered. It was rechecked and remained the same. It is not clinically significant.' (Site from DM).		29 Sep 2020 19:51:34
User opened query 'CDM RQ: Please confirm if this result should be considered clinically significant or not.' (Site from DM).		24 Sep 2020 14:08:09
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).		24 Sep 2020 14:08:09
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 'correct as entered. temp rechecked and remained the same.' (Site from DM).		21 Sep 2020 21:02:53
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).		21 Sep 2020 12:43:23
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 12:43:21
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. It was rechecked and remained the same.' (Site from System).		17 Sep 2020 15:03:39

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Oral (Oral)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '60'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'bpm'	System	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '14'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'breaths/min'	System	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '121'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'mmHg'	System	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '63'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'mmHg'	System	18 Aug 2020 18:59:43

US3442024

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:47:07
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:59:52

US3442024

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:47:07
User entered '18 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 18:59:52

US3442024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:43:15

US3442024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:43:15

US3442024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

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 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:43:15

US3442024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'MRNA-1273 OR PLACEBO'	System	18 Aug 2020 17:43:15

US3442024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '18 Aug 2020'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:43:15

US3442024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '12:35'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:43:15

US3442024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered '18 Aug 2020 12:35'	System	18 Aug 2020 17:43:15

US3442024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 17:43:15

US3442024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'ONCE'	System	18 Aug 2020 17:43:15

US3442024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'INTRAMUSCULAR'	System	18 Aug 2020 17:43:15

US3442024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 19:00:13

US3442024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '18 Aug 2020'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 19:00:13

US3442024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '11:50'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 19:00:13

US3442024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered '18 Aug 2020 11:50'	System	18 Aug 2020 19:00:13

US3442024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:42:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '18 Aug 2020'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 19:00:29

US3442024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 19:00:29

US3442024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 19:00:29

US3442024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '11:56'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 19:00:29

US3442024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered '18 Aug 2020 11:56'	System	18 Aug 2020 19:00:29

US3442024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:42:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 19:00:29

US3442024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:42:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 19:00:29

US3442024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:42:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 19:00:29

US3442024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:42:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered empty.	System	18 Aug 2020 19:00:29

US3442024

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 16:17:00

US3442024

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'I'	System	26 Aug 2020 16:17:00

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T13:22:32', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'e0561b6b-e39f-45a1-be5f-6d0620da9310'	System	18 Aug 2020 18:23:15
User entered 'Yes (Y)'	System	18 Aug 2020 18:23:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T13:22:39', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'e0561b6b-e39f-45a1-be5f-6d0620da9310'	System	18 Aug 2020 18:23:15
User entered '96.4'	System	18 Aug 2020 18:23:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T13:23:06', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'e0561b6b-e39f-45a1-be5f-6d0620da9310'	System	18 Aug 2020 18:23:15
User entered 'No (N)'	System	18 Aug 2020 18:23:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T13:23:13', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'e0561b6b-e39f-45a1-be5f-6d0620da9310'	System	18 Aug 2020 18:23:15
User entered '18 Aug 2020 13:23'	System	18 Aug 2020 18:23:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '18 Aug 2020 12:55'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '18 Aug 2020 15:25'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T17:48:22', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '30854749-9670-4b9e-93c6-2f447dabbbf18'	System	18 Aug 2020 22:48:44
User entered 'Yes (Y)'	System	18 Aug 2020 22:48:44

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T17:48:29', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '30854749-9670-4b9e-93c6-2f447dabbbf18'	System	18 Aug 2020 22:48:44
User entered '97.3'	System	18 Aug 2020 22:48:44

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T17:48:33', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '30854749-9670-4b9e-93c6-2f447dabbbf18'	System	18 Aug 2020 22:48:44
User entered 'No (N)'	System	18 Aug 2020 22:48:44

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T17:48:41', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '30854749-9670-4b9e-93c6-2f447dabbbf18'	System	18 Aug 2020 22:48:44
User entered '18 Aug 2020 17:48'	System	18 Aug 2020 22:48:44

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '18 Aug 2020 16:20'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 2'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:40:35', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'dbd2b89c-68db-41d0-9830-588f2d1fa164'	System	19 Aug 2020 21:42:05
User entered 'Yes (Y)'	System	19 Aug 2020 21:42:05

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:41:17', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'dbd2b89c-68db-41d0-9830-588f2d1fa164'	System	19 Aug 2020 21:42:05
User entered '96.6'	System	19 Aug 2020 21:42:05

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:41:32', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'dbd2b89c-68db-41d0-9830-588f2d1fa164'	System	19 Aug 2020 21:42:05
User entered 'Yes (Y)'	System	19 Aug 2020 21:42:05

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject contacted, logs updated' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:07:21
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	19 Aug 2020 23:06:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:41:51', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'dbd2b89c-68db-41d0-9830-588f2d1fa164'	System	19 Aug 2020 21:42:05
User entered '1'	System	19 Aug 2020 21:42:05

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:41:51', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'dbd2b89c-68db-41d0-9830-588f2d1fa164'	System	19 Aug 2020 21:42:05
User entered '0'	System	19 Aug 2020 21:42:05

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:42:02', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'dbd2b89c-68db-41d0-9830-588f2d1fa164'	System	19 Aug 2020 21:42:05
User entered '19 Aug 2020 16:42'	System	19 Aug 2020 21:42:05

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 3'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-20T16:52:39', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '623b4c6c-f20c-4c2f-9caa-da44b6b33918'	System	20 Aug 2020 21:52:58
User entered 'Yes (Y)'	System	20 Aug 2020 21:52:58

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-20T16:52:45', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '623b4c6c-f20c-4c2f-9caa-da44b6b33918'	System	20 Aug 2020 21:52:58
User entered '97.0'	System	20 Aug 2020 21:52:58

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-20T16:52:48', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '623b4c6c-f20c-4c2f-9caa-da44b6b33918'	System	20 Aug 2020 21:52:58
User entered 'No (N)'	System	20 Aug 2020 21:52:58

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-20T16:52:54', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '623b4c6c-f20c-4c2f-9caa-da44b6b33918'	System	20 Aug 2020 21:52:58
User entered '20 Aug 2020 16:52'	System	20 Aug 2020 21:52:58

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 4'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-21T15:49:21', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '4207649d-238c-4cd6-ad59-025cd30e2060'	System	21 Aug 2020 20:50:12
User entered 'Yes (Y)'	System	21 Aug 2020 20:50:12

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-21T15:50:03', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '4207649d-238c-4cd6-ad59-025cd30e2060'	System	21 Aug 2020 20:50:12
User entered '97.9'	System	21 Aug 2020 20:50:12

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-21T15:50:07', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '4207649d-238c-4cd6-ad59-025cd30e2060'	System	21 Aug 2020 20:50:12
User entered 'No (N)'	System	21 Aug 2020 20:50:12

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-21T15:50:10', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '4207649d-238c-4cd6-ad59-025cd30e2060'	System	21 Aug 2020 20:50:12
User entered '21 Aug 2020 15:50'	System	21 Aug 2020 20:50:12

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 5'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-22T19:04:15', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '3d052af0-31e3-4487-abd7-af3f6fd9ac3d'	System	23 Aug 2020 00:04:33
User entered 'Yes (Y)'	System	23 Aug 2020 00:04:33

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-22T19:04:21', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '3d052af0-31e3-4487-abd7-af3f6fd9ac3d'	System	23 Aug 2020 00:04:33
User entered '96.9'	System	23 Aug 2020 00:04:33

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-22T19:04:26', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '3d052af0-31e3-4487-abd7-af3f6fd9ac3d'	System	23 Aug 2020 00:04:33
User entered 'No (N)'	System	23 Aug 2020 00:04:33

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-22T19:04:29', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '3d052af0-31e3-4487-abd7-af3f6fd9ac3d'	System	23 Aug 2020 00:04:33
User entered '22 Aug 2020 19:04'	System	23 Aug 2020 00:04:33

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 6'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-23T13:16:59', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '4712d545-874c-488f-9911-992ec738e105'	System	23 Aug 2020 18:18:14
User entered 'Yes (Y)'	System	23 Aug 2020 18:18:14

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-23T13:18:03', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '4712d545-874c-488f-9911-992ec738e105'	System	23 Aug 2020 18:18:14
User entered '96.3'	System	23 Aug 2020 18:18:14

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-23T13:18:06', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '4712d545-874c-488f-9911-992ec738e105'	System	23 Aug 2020 18:18:14
User entered 'No (N)'	System	23 Aug 2020 18:18:14

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-23T13:18:11', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '4712d545-874c-488f-9911-992ec738e105'	System	23 Aug 2020 18:18:14
User entered '23 Aug 2020 13:18'	System	23 Aug 2020 18:18:14

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 7'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-24T13:40:06', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'd6e25157-467f-4cd5-aa8b-c7b008e74a35'	System	24 Aug 2020 18:40:23
User entered 'Yes (Y)'	System	24 Aug 2020 18:40:23

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-24T13:40:14', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'd6e25157-467f-4cd5-aa8b-c7b008e74a35'	System	24 Aug 2020 18:40:23
User entered '95.9'	System	24 Aug 2020 18:40:23

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-24T13:40:17', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'd6e25157-467f-4cd5-aa8b-c7b008e74a35'	System	24 Aug 2020 18:40:23
User entered 'No (N)'	System	24 Aug 2020 18:40:23

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-24T13:40:21', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'd6e25157-467f-4cd5-aa8b-c7b008e74a35'	System	24 Aug 2020 18:40:23
User entered '24 Aug 2020 13:40'	System	24 Aug 2020 18:40:23

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T13:23:28', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '625cd1af-2845-4f6c-9eaa-c657377d24a1'	System	18 Aug 2020 18:23:55
User entered 'None (1)'	System	18 Aug 2020 18:23:55

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T13:23:39', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '625cd1af-2845-4f6c-9eaa-c657377d24a1'	System	18 Aug 2020 18:23:55
User entered 'No (N)'	System	18 Aug 2020 18:23:55

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T13:23:43', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '625cd1af-2845-4f6c-9eaa-c657377d24a1'	System	18 Aug 2020 18:23:55
User entered 'No (N)'	System	18 Aug 2020 18:23:55

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T13:23:50', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '625cd1af-2845-4f6c-9eaa-c657377d24a1'	System	18 Aug 2020 18:23:55
User entered 'None (1)'	System	18 Aug 2020 18:23:55

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T13:23:54', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '625cd1af-2845-4f6c-9eaa-c657377d24a1'	System	18 Aug 2020 18:23:55
User entered '18 Aug 2020 13:23'	System	18 Aug 2020 18:23:55

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '18 Aug 2020 12:55'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '18 Aug 2020 15:25'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T17:49:00', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '2cc7591c-4a2a-41ed-8d26-7b275a9471ba'	System	18 Aug 2020 22:49:25
User entered 'None (1)'	System	18 Aug 2020 22:49:25

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T17:49:03', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '2cc7591c-4a2a-41ed-8d26-7b275a9471ba'	System	18 Aug 2020 22:49:25
User entered 'No (N)'	System	18 Aug 2020 22:49:25

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T17:49:10', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '2cc7591c-4a2a-41ed-8d26-7b275a9471ba'	System	18 Aug 2020 22:49:25
User entered 'No (N)'	System	18 Aug 2020 22:49:25

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T17:49:14', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '2cc7591c-4a2a-41ed-8d26-7b275a9471ba'	System	18 Aug 2020 22:49:25
User entered 'None (1)'	System	18 Aug 2020 22:49:25

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T17:49:20', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '2cc7591c-4a2a-41ed-8d26-7b275a9471ba'	System	18 Aug 2020 22:49:25
User entered '18 Aug 2020 17:49'	System	18 Aug 2020 22:49:25

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '18 Aug 2020 16:20'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 2'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:42:08', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '304e7dc4-802e-4583-b245-575608a14c4e'	System	19 Aug 2020 21:42:26
User entered 'None (1)'	System	19 Aug 2020 21:42:26

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:42:11', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '304e7dc4-802e-4583-b245-575608a14c4e'	System	19 Aug 2020 21:42:26
User entered 'No (N)'	System	19 Aug 2020 21:42:26

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:42:14', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '304e7dc4-802e-4583-b245-575608a14c4e'	System	19 Aug 2020 21:42:26
User entered 'No (N)'	System	19 Aug 2020 21:42:26

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:42:19', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '304e7dc4-802e-4583-b245-575608a14c4e'	System	19 Aug 2020 21:42:26
User entered 'None (1)'	System	19 Aug 2020 21:42:26

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:42:23', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '304e7dc4-802e-4583-b245-575608a14c4e'	System	19 Aug 2020 21:42:26
User entered '19 Aug 2020 16:42'	System	19 Aug 2020 21:42:26

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 3'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-20T16:53:04', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '327fb1cf-b020-4596-801c-da5d6515c073'	System	20 Aug 2020 21:53:21
User entered 'None (1)'	System	20 Aug 2020 21:53:21

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-20T16:53:07', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '327fb1cf-b020-4596-801c-da5d6515c073'	System	20 Aug 2020 21:53:21
User entered 'No (N)'	System	20 Aug 2020 21:53:21

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-20T16:53:10', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '327fb1cf-b020-4596-801c-da5d6515c073'	System	20 Aug 2020 21:53:21
User entered 'No (N)'	System	20 Aug 2020 21:53:21

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-20T16:53:16', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '327fb1cf-b020-4596-801c-da5d6515c073'	System	20 Aug 2020 21:53:21
User entered 'None (1)'	System	20 Aug 2020 21:53:21

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-20T16:53:19', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '327fb1cf-b020-4596-801c-da5d6515c073'	System	20 Aug 2020 21:53:21
User entered '20 Aug 2020 16:53'	System	20 Aug 2020 21:53:21

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 4'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-21T15:50:17', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'f92e9155-b2cb-40f6-976f-da17bacefb83'	System	21 Aug 2020 20:50:31
User entered 'None (1)'	System	21 Aug 2020 20:50:31

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-21T15:50:20', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'f92e9155-b2cb-40f6-976f-da17bacefb83'	System	21 Aug 2020 20:50:31
User entered 'No (N)'	System	21 Aug 2020 20:50:31

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-21T15:50:23', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'f92e9155-b2cb-40f6-976f-da17bacefb83'	System	21 Aug 2020 20:50:31
User entered 'No (N)'	System	21 Aug 2020 20:50:31

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-21T15:50:27', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'f92e9155-b2cb-40f6-976f-da17bacefb83'	System	21 Aug 2020 20:50:31
User entered 'None (1)'	System	21 Aug 2020 20:50:31

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-21T15:50:30', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'f92e9155-b2cb-40f6-976f-da17bacefb83'	System	21 Aug 2020 20:50:31
User entered '21 Aug 2020 15:50'	System	21 Aug 2020 20:50:31

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 5'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-22T19:04:34', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '11acaa99-2535-47ac-8b81-c5e88f5f88a1'	System	23 Aug 2020 00:04:49
User entered 'None (1)'	System	23 Aug 2020 00:04:49

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-22T19:04:36', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '11acaa99-2535-47ac-8b81-c5e88f5f88a1'	System	23 Aug 2020 00:04:49
User entered 'No (N)'	System	23 Aug 2020 00:04:49

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-22T19:04:39', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '11acaa99-2535-47ac-8b81-c5e88f5f88a1'	System	23 Aug 2020 00:04:49
User entered 'No (N)'	System	23 Aug 2020 00:04:49

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-22T19:04:41', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '11acaa99-2535-47ac-8b81-c5e88f5f88a1'	System	23 Aug 2020 00:04:49
User entered 'None (1)'	System	23 Aug 2020 00:04:49

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-22T19:04:45', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '11acaa99-2535-47ac-8b81-c5e88f5f88a1'	System	23 Aug 2020 00:04:49
User entered '22 Aug 2020 19:04'	System	23 Aug 2020 00:04:49

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 6'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-23T13:18:16', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7eb98c50-88e8-4822-ad34-1bc33b52a6fa'	System	23 Aug 2020 18:18:32
User entered 'None (1)'	System	23 Aug 2020 18:18:32

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-23T13:18:19', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7eb98c50-88e8-4822-ad34-1bc33b52a6fa'	System	23 Aug 2020 18:18:32
User entered 'No (N)'	System	23 Aug 2020 18:18:32

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-23T13:18:23', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7eb98c50-88e8-4822-ad34-1bc33b52a6fa'	System	23 Aug 2020 18:18:32
User entered 'No (N)'	System	23 Aug 2020 18:18:32

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-23T13:18:26', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7eb98c50-88e8-4822-ad34-1bc33b52a6fa'	System	23 Aug 2020 18:18:32
User entered 'None (1)'	System	23 Aug 2020 18:18:32

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-23T13:18:29', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7eb98c50-88e8-4822-ad34-1bc33b52a6fa'	System	23 Aug 2020 18:18:32
User entered '23 Aug 2020 13:18'	System	23 Aug 2020 18:18:32

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 7'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-24T13:40:25', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '475830cb-06d6-475d-ae53-a478320106be'	System	24 Aug 2020 18:40:37
User entered 'None (1)'	System	24 Aug 2020 18:40:37

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-24T13:40:27', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '475830cb-06d6-475d-ae53-a478320106be'	System	24 Aug 2020 18:40:37
User entered 'No (N)'	System	24 Aug 2020 18:40:37

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-24T13:40:30', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '475830cb-06d6-475d-ae53-a478320106be'	System	24 Aug 2020 18:40:37
User entered 'No (N)'	System	24 Aug 2020 18:40:37

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-24T13:40:33', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '475830cb-06d6-475d-ae53-a478320106be'	System	24 Aug 2020 18:40:37
User entered 'None (1)'	System	24 Aug 2020 18:40:37

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-24T13:40:36', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '475830cb-06d6-475d-ae53-a478320106be'	System	24 Aug 2020 18:40:37
User entered '24 Aug 2020 13:40'	System	24 Aug 2020 18:40:37

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T13:24:03', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'aa3e8f76-821f-4346-a716-1181b8bf3f25'	System	18 Aug 2020 18:24:36
User entered 'None (0)'	System	18 Aug 2020 18:24:36

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T13:24:06', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'aa3e8f76-821f-4346-a716-1181b8bf3f25'	System	18 Aug 2020 18:24:36
User entered 'None (0)'	System	18 Aug 2020 18:24:36

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T13:24:09', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'aa3e8f76-821f-4346-a716-1181b8bf3f25'	System	18 Aug 2020 18:24:36
User entered 'None (0)'	System	18 Aug 2020 18:24:36

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T13:24:12', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'aa3e8f76-821f-4346-a716-1181b8bf3f25'	System	18 Aug 2020 18:24:36
User entered 'None (0)'	System	18 Aug 2020 18:24:36

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T13:24:15', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'aa3e8f76-821f-4346-a716-1181b8bf3f25'	System	18 Aug 2020 18:24:36
User entered 'None (0)'	System	18 Aug 2020 18:24:36

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T13:24:17', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'aa3e8f76-821f-4346-a716-1181b8bf3f25'	System	18 Aug 2020 18:24:36
User entered 'None (0)'	System	18 Aug 2020 18:24:36

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T13:24:22', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'aa3e8f76-821f-4346-a716-1181b8bf3f25'	System	18 Aug 2020 18:24:36
User entered 'No (N)'	System	18 Aug 2020 18:24:36

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T13:24:25', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'aa3e8f76-821f-4346-a716-1181b8bf3f25'	System	18 Aug 2020 18:24:36
User entered '18 Aug 2020 13:24'	System	18 Aug 2020 18:24:36

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '18 Aug 2020 12:55'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '18 Aug 2020 15:25'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T17:49:27', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '4fcec1d4-1743-4cd4-a7b2-dc6bc269baa5'	System	18 Aug 2020 22:50:02
User entered 'None (0)'	System	18 Aug 2020 22:50:02

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T17:49:30', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '4fcec1d4-1743-4cd4-a7b2-dc6bc269baa5'	System	18 Aug 2020 22:50:02
User entered 'None (0)'	System	18 Aug 2020 22:50:02

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T17:49:34', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '4fcec1d4-1743-4cd4-a7b2-dc6bc269baa5'	System	18 Aug 2020 22:50:02
User entered 'None (0)'	System	18 Aug 2020 22:50:02

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T17:49:42', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '4fcec1d4-1743-4cd4-a7b2-dc6bc269baa5'	System	18 Aug 2020 22:50:02
User entered 'None (0)'	System	18 Aug 2020 22:50:02

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T17:49:45', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '4fcec1d4-1743-4cd4-a7b2-dc6bc269baa5'	System	18 Aug 2020 22:50:02
User entered 'None (0)'	System	18 Aug 2020 22:50:02

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T17:49:48', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '4fcec1d4-1743-4cd4-a7b2-dc6bc269baa5'	System	18 Aug 2020 22:50:02
User entered 'None (0)'	System	18 Aug 2020 22:50:02

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T17:49:55', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '4fcec1d4-1743-4cd4-a7b2-dc6bc269baa5'	System	18 Aug 2020 22:50:02
User entered 'No (N)'	System	18 Aug 2020 22:50:02

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-18T17:49:58', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '4fcec1d4-1743-4cd4-a7b2-dc6bc269baa5'	System	18 Aug 2020 22:50:02
User entered '18 Aug 2020 17:49'	System	18 Aug 2020 22:50:02

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '18 Aug 2020 16:20'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 2'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:42:29', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '8f49daea-2bf0-423a-9620-1691bf8ade8e'	System	19 Aug 2020 21:43:10
User entered 'None (0)'	System	19 Aug 2020 21:43:10

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:42:34', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '8f49daea-2bf0-423a-9620-1691bf8ade8e'	System	19 Aug 2020 21:43:10
User entered 'None (0)'	System	19 Aug 2020 21:43:10

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:42:37', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '8f49daea-2bf0-423a-9620-1691bf8ade8e'	System	19 Aug 2020 21:43:10
User entered 'None (0)'	System	19 Aug 2020 21:43:10

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:42:53', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '8f49daea-2bf0-423a-9620-1691bf8ade8e'	System	19 Aug 2020 21:43:10
User entered 'None (0)'	System	19 Aug 2020 21:43:10

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:42:56', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '8f49daea-2bf0-423a-9620-1691bf8ade8e'	System	19 Aug 2020 21:43:10
User entered 'None (0)'	System	19 Aug 2020 21:43:10

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:42:59', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '8f49daea-2bf0-423a-9620-1691bf8ade8e'	System	19 Aug 2020 21:43:10
User entered 'None (0)'	System	19 Aug 2020 21:43:10

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:43:03', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '8f49daea-2bf0-423a-9620-1691bf8ade8e'	System	19 Aug 2020 21:43:10
User entered 'No (N)'	System	19 Aug 2020 21:43:10

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-19T16:43:07', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '8f49daea-2bf0-423a-9620-1691bf8ade8e'	System	19 Aug 2020 21:43:10
User entered '19 Aug 2020 16:43'	System	19 Aug 2020 21:43:10

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 3'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-20T16:53:25', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '1770eec0-646b-4dde-9805-49147f7ab515'	System	20 Aug 2020 21:53:48
User entered 'None (0)'	System	20 Aug 2020 21:53:48

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-20T16:53:27', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '1770eec0-646b-4dde-9805-49147f7ab515'	System	20 Aug 2020 21:53:48
User entered 'None (0)'	System	20 Aug 2020 21:53:48

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-20T16:53:29', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '1770eec0-646b-4dde-9805-49147f7ab515'	System	20 Aug 2020 21:53:48
User entered 'None (0)'	System	20 Aug 2020 21:53:48

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-20T16:53:32', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '1770eec0-646b-4dde-9805-49147f7ab515'	System	20 Aug 2020 21:53:48
User entered 'None (0)'	System	20 Aug 2020 21:53:48

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-20T16:53:34', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '1770eec0-646b-4dde-9805-49147f7ab515'	System	20 Aug 2020 21:53:48
User entered 'None (0)'	System	20 Aug 2020 21:53:48

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-20T16:53:36', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '1770eec0-646b-4dde-9805-49147f7ab515'	System	20 Aug 2020 21:53:48
User entered 'None (0)'	System	20 Aug 2020 21:53:48

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-20T16:53:40', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '1770eec0-646b-4dde-9805-49147f7ab515'	System	20 Aug 2020 21:53:48
User entered 'No (N)'	System	20 Aug 2020 21:53:48

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-20T16:53:43', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '1770eec0-646b-4dde-9805-49147f7ab515'	System	20 Aug 2020 21:53:48
User entered '20 Aug 2020 16:53'	System	20 Aug 2020 21:53:48

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 4'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-21T15:50:35', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '3d8b73b9-7719-437a-9296-d22235a7fb25'	System	21 Aug 2020 20:50:54
User entered 'None (0)'	System	21 Aug 2020 20:50:54

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-21T15:50:37', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '3d8b73b9-7719-437a-9296-d22235a7fb25'	System	21 Aug 2020 20:50:54
User entered 'None (0)'	System	21 Aug 2020 20:50:54

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-21T15:50:39', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '3d8b73b9-7719-437a-9296-d22235a7fb25'	System	21 Aug 2020 20:50:54
User entered 'None (0)'	System	21 Aug 2020 20:50:54

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-21T15:50:42', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '3d8b73b9-7719-437a-9296-d22235a7fb25'	System	21 Aug 2020 20:50:54
User entered 'None (0)'	System	21 Aug 2020 20:50:54

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-21T15:50:44', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '3d8b73b9-7719-437a-9296-d22235a7fb25'	System	21 Aug 2020 20:50:54
User entered 'None (0)'	System	21 Aug 2020 20:50:54

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-21T15:50:47', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '3d8b73b9-7719-437a-9296-d22235a7fb25'	System	21 Aug 2020 20:50:54
User entered 'None (0)'	System	21 Aug 2020 20:50:54

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-21T15:50:50', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '3d8b73b9-7719-437a-9296-d22235a7fb25'	System	21 Aug 2020 20:50:54
User entered 'No (N)'	System	21 Aug 2020 20:50:54

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-21T15:50:52', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '3d8b73b9-7719-437a-9296-d22235a7fb25'	System	21 Aug 2020 20:50:54
User entered '21 Aug 2020 15:50'	System	21 Aug 2020 20:50:54

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 5'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-22T19:04:51', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '790436d0-aa4f-4920-930c-8331a0e45343'	System	23 Aug 2020 00:05:10
User entered 'None (0)'	System	23 Aug 2020 00:05:10

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-22T19:04:53', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '790436d0-aa4f-4920-930c-8331a0e45343'	System	23 Aug 2020 00:05:10
User entered 'None (0)'	System	23 Aug 2020 00:05:10

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-22T19:04:55', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '790436d0-aa4f-4920-930c-8331a0e45343'	System	23 Aug 2020 00:05:10
User entered 'None (0)'	System	23 Aug 2020 00:05:10

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-22T19:04:57', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '790436d0-aa4f-4920-930c-8331a0e45343'	System	23 Aug 2020 00:05:10
User entered 'None (0)'	System	23 Aug 2020 00:05:10

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-22T19:05:00', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '790436d0-aa4f-4920-930c-8331a0e45343'	System	23 Aug 2020 00:05:10
User entered 'None (0)'	System	23 Aug 2020 00:05:10

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-22T19:05:02', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '790436d0-aa4f-4920-930c-8331a0e45343'	System	23 Aug 2020 00:05:10
User entered 'None (0)'	System	23 Aug 2020 00:05:10

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-22T19:05:05', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '790436d0-aa4f-4920-930c-8331a0e45343'	System	23 Aug 2020 00:05:10
User entered 'No (N)'	System	23 Aug 2020 00:05:10

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-22T19:05:08', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '790436d0-aa4f-4920-930c-8331a0e45343'	System	23 Aug 2020 00:05:10
User entered '22 Aug 2020 19:05'	System	23 Aug 2020 00:05:10

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 6'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-23T13:18:34', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'c740dbfc-e846-48f2-8c92-a20652dde742'	System	23 Aug 2020 18:18:59
User entered 'None (0)'	System	23 Aug 2020 18:18:59

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-23T13:18:36', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'c740dbfc-e846-48f2-8c92-a20652dde742'	System	23 Aug 2020 18:18:59
User entered 'None (0)'	System	23 Aug 2020 18:18:59

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-23T13:18:39', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'c740dbfc-e846-48f2-8c92-a20652dde742'	System	23 Aug 2020 18:18:59
User entered 'None (0)'	System	23 Aug 2020 18:18:59

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-23T13:18:42', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'c740dbfc-e846-48f2-8c92-a20652dde742'	System	23 Aug 2020 18:18:59
User entered 'None (0)'	System	23 Aug 2020 18:18:59

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-23T13:18:45', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'c740dbfc-e846-48f2-8c92-a20652dde742'	System	23 Aug 2020 18:18:59
User entered 'None (0)'	System	23 Aug 2020 18:18:59

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-23T13:18:47', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'c740dbfc-e846-48f2-8c92-a20652dde742'	System	23 Aug 2020 18:18:59
User entered 'None (0)'	System	23 Aug 2020 18:18:59

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-23T13:18:52', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'c740dbfc-e846-48f2-8c92-a20652dde742'	System	23 Aug 2020 18:18:59
User entered 'No (N)'	System	23 Aug 2020 18:18:59

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-23T13:18:56', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'c740dbfc-e846-48f2-8c92-a20652dde742'	System	23 Aug 2020 18:18:59
User entered '23 Aug 2020 13:18'	System	23 Aug 2020 18:18:59

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 7'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-24T13:40:42', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '42be0c4a-0f62-4fed-b38f-aa86e15ff9f8'	System	24 Aug 2020 18:41:04
User entered 'None (0)'	System	24 Aug 2020 18:41:04

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-24T13:40:44', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '42be0c4a-0f62-4fed-b38f-aa86e15ff9f8'	System	24 Aug 2020 18:41:04
User entered 'None (0)'	System	24 Aug 2020 18:41:04

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-24T13:40:46', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '42be0c4a-0f62-4fed-b38f-aa86e15ff9f8'	System	24 Aug 2020 18:41:04
User entered 'None (0)'	System	24 Aug 2020 18:41:04

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-24T13:40:49', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '42be0c4a-0f62-4fed-b38f-aa86e15ff9f8'	System	24 Aug 2020 18:41:04
User entered 'None (0)'	System	24 Aug 2020 18:41:04

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-24T13:40:51', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '42be0c4a-0f62-4fed-b38f-aa86e15ff9f8'	System	24 Aug 2020 18:41:04
User entered 'None (0)'	System	24 Aug 2020 18:41:04

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-24T13:40:53', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '42be0c4a-0f62-4fed-b38f-aa86e15ff9f8'	System	24 Aug 2020 18:41:04
User entered 'None (0)'	System	24 Aug 2020 18:41:04

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-24T13:40:57', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '42be0c4a-0f62-4fed-b38f-aa86e15ff9f8'	System	24 Aug 2020 18:41:04
User entered 'No (N)'	System	24 Aug 2020 18:41:04

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-08-24T13:41:00', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '42be0c4a-0f62-4fed-b38f-aa86e15ff9f8'	System	24 Aug 2020 18:41:04
User entered '24 Aug 2020 13:41'	System	24 Aug 2020 18:41:04

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 17:43:15

US3442024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	28 Aug 2020 19:46:20

US3442024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '28 Aug 2020'	(b) (4) Melody Dufrene (b) (4)	28 Aug 2020 19:46:20
	(b) (4)	

US3442024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Melody Dufrene (b) (4)	28 Aug 2020 19:46:20

US3442024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:11:17
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:46:20

US3442024

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	28 Aug 2020 19:46:26

US3442024

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'I'	System	28 Aug 2020 19:46:26

US3442024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:23:04

US3442024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '1 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:23:04

US3442024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:23:04

US3442024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:23:04

US3442024

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:23:10

US3442024

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'I'	System	01 Sep 2020 17:23:10

US3442024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:47:27

US3442024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:47:27

US3442024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:47:27

US3442024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:47:27

US3442024

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:47:34

US3442024

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'I'	System	10 Sep 2020 18:47:34

US3442024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	17 Sep 2020 15:00:31

US3442024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '17 Sep 2020'	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:00:31

US3442024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[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 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Clinic (Clinic)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	17 Sep 2020 15:00:31

US3442024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered 'VISIT2'	System	17 Sep 2020 15:00:31

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User accepted default value 'Pre-Dose (PREDOSE)'	Melody Dufrene (b) (4) (b) (4)	17 Sep 2020 15:02:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:02:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '17 Sep 2020'	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:02:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '09:36'	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:02:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered '17 Sep 2020 09:36'	System	17 Sep 2020 15:02:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '97.9' F	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:02:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Oral (Oral)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	17 Sep 2020 15:02:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:02:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '67'	(b) (4) Melody Dufrene (b) (4) (b) (4)	17 Sep 2020 15:02:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered 'bpm'	System	17 Sep 2020 15:02:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '12'	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:02:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered 'breaths/min'	System	17 Sep 2020 15:02:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '97'	(b) (4) Melody Dufrene (b) (4) (b) (4)	17 Sep 2020 15:02:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered 'mmHg'	System	17 Sep 2020 15:02:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:11:17
User entered '63'	Melody Dufrene (b) (4) (b) (4)	17 Sep 2020 15:02:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered 'mmHg'	System	17 Sep 2020 15:02:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User accepted default value 'Post-Dose (POSTDOSE)'		17 Sep 2020 16:24:11

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:24:11

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:24:11

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '10:53'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:24:11

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered '17 Sep 2020 10:53'	System	17 Sep 2020 16:24:11

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:24:11

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:24:11

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:24:11

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '66'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:24:11

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered 'bpm'	System	17 Sep 2020 16:24:11

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '12'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:24:11

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered 'breaths/min'	System	17 Sep 2020 16:24:11

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '126'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:24:11

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered 'mmHg'	System	17 Sep 2020 16:24:11

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '68'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:24:11

US3442024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered 'mmHg'	System	17 Sep 2020 16:24:11

US3442024

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:00:47

US3442024

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '17 Sep 2020'	(b) (4) Melody Dufrene (b) (4) (b) (4)	17 Sep 2020 15:00:47

US3442024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:36:09

US3442024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:36:09

US3442024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

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 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:36:09

US3442024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 15:36:09

US3442024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '17 Sep 2020'	(b) (4) Melody Dufrene (b) (4) (b) (4)	17 Sep 2020 15:36:09

US3442024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '10:20'	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:36:09

US3442024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered '17 Sep 2020 10:20'	System	17 Sep 2020 15:36:09

US3442024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:36:09

US3442024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered 'ONCE'	System	17 Sep 2020 15:36:09

US3442024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 15:36:09

US3442024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:01:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '17 Sep 2020'	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:01:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '09:46'	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:01:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered '17 Sep 2020 09:46'	System	17 Sep 2020 15:01:10

US3442024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:42:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '17 Sep 2020'	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:01:29

US3442024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Melody Dufrene (b) (4) (b) (4)	17 Sep 2020 15:01:29

US3442024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	17 Sep 2020 15:01:29

US3442024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '09:40'	(b) (4) Melody Dufrene (b) (4) (b) (4)	17 Sep 2020 15:01:29

US3442024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:42:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered '17 Sep 2020 09:40'	System	17 Sep 2020 15:01:29

US3442024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:42:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Melody Dufrene (b) (4) (b) (4)	17 Sep 2020 15:01:29

US3442024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:42:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	17 Sep 2020 15:01:29

US3442024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:42:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:01:29

US3442024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:42:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered empty.	System	17 Sep 2020 15:01:29

US3442024

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	17 Sep 2020 15:00:36

US3442024

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered '1'	System	17 Sep 2020 15:00:36

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T10:54:16', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '44e970e1-1984-4f60-ad78-4626f4556842'	System	17 Sep 2020 15:54:38
User entered 'Yes (Y)'	System	17 Sep 2020 15:54:38

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T10:54:24', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '44e970e1-1984-4f60-ad78-4626f4556842'	System	17 Sep 2020 15:54:38
User entered '97.7'	System	17 Sep 2020 15:54:38

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T10:54:30', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '44e970e1-1984-4f60-ad78-4626f4556842'	System	17 Sep 2020 15:54:38
User entered 'No (N)'	System	17 Sep 2020 15:54:38

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T10:54:34', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '44e970e1-1984-4f60-ad78-4626f4556842'	System	17 Sep 2020 15:54:38
User entered '17 Sep 2020 10:54'	System	17 Sep 2020 15:54:38

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '17 Sep 2020 10:40'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '17 Sep 2020 13:10'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T15:55:27', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '76e02a02-3d4b-4ce2-98f3-dec3671eb4ec'	System	17 Sep 2020 20:56:24
User entered 'Yes (Y)'	System	17 Sep 2020 20:56:24

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T15:56:08', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '76e02a02-3d4b-4ce2-98f3-dec3671eb4ec'	System	17 Sep 2020 20:56:24
User entered '97.2'	System	17 Sep 2020 20:56:24

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T15:56:13', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '76e02a02-3d4b-4ce2-98f3-dec3671eb4ec'	System	17 Sep 2020 20:56:24
User entered 'No (N)'	System	17 Sep 2020 20:56:24

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T15:56:18', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '76e02a02-3d4b-4ce2-98f3-dec3671eb4ec'	System	17 Sep 2020 20:56:24
User entered '17 Sep 2020 15:56'	System	17 Sep 2020 20:56:24

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '17 Sep 2020 14:05'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 2'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-18T12:32:04', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'cd6e1266-99cc-47ec-8e5d-e19e1e3cc86f'	System	18 Sep 2020 17:32:24
User entered 'Yes (Y)'	System	18 Sep 2020 17:32:24

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-18T12:32:10', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'cd6e1266-99cc-47ec-8e5d-e19e1e3cc86f'	System	18 Sep 2020 17:32:24
User entered '98.3'	System	18 Sep 2020 17:32:24

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-18T12:32:14', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'cd6e1266-99cc-47ec-8e5d-e19e1e3cc86f'	System	18 Sep 2020 17:32:24
User entered 'No (N)'	System	18 Sep 2020 17:32:24

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-18T12:32:19', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'cd6e1266-99cc-47ec-8e5d-e19e1e3cc86f'	System	18 Sep 2020 17:32:24
User entered '18 Sep 2020 12:32'	System	18 Sep 2020 17:32:24

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 3'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-19T18:51:16', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'adf31425-526f-4742-8f2b-54f7fdea0ce8'	System	19 Sep 2020 23:51:36
User entered 'Yes (Y)'	System	19 Sep 2020 23:51:36

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-19T18:51:23', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'adf31425-526f-4742-8f2b-54f7fdea0ce8'	System	19 Sep 2020 23:51:36
User entered '97.8'	System	19 Sep 2020 23:51:36

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-19T18:51:28', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'adf31425-526f-4742-8f2b-54f7fdea0ce8'	System	19 Sep 2020 23:51:36
User entered 'No (N)'	System	19 Sep 2020 23:51:36

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-19T18:51:32', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'adf31425-526f-4742-8f2b-54f7fdea0ce8'	System	19 Sep 2020 23:51:36
User entered '19 Sep 2020 18:51'	System	19 Sep 2020 23:51:36

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 4'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-20T12:19:59', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7a96e4ac-82dc-4f23-bd93-a97424c3b254'	System	20 Sep 2020 17:20:31
User entered 'Yes (Y)'	System	20 Sep 2020 17:20:31

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-20T12:20:20', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7a96e4ac-82dc-4f23-bd93-a97424c3b254'	System	20 Sep 2020 17:20:31
User entered '98.3'	System	20 Sep 2020 17:20:31

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-20T12:20:23', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7a96e4ac-82dc-4f23-bd93-a97424c3b254'	System	20 Sep 2020 17:20:31
User entered 'No (N)'	System	20 Sep 2020 17:20:31

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-20T12:20:27', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7a96e4ac-82dc-4f23-bd93-a97424c3b254'	System	20 Sep 2020 17:20:31
User entered '20 Sep 2020 12:20'	System	20 Sep 2020 17:20:31

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 5'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-21T15:13:34', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7aedaabe-76d8-4fbf-b3cd-8a0e447332b3'	System	21 Sep 2020 20:13:50
User entered 'Yes (Y)'	System	21 Sep 2020 20:13:50

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-21T15:13:42', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7aedaabe-76d8-4fbf-b3cd-8a0e447332b3'	System	21 Sep 2020 20:13:50
User entered '97.9'	System	21 Sep 2020 20:13:50

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-21T15:13:45', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7aedaabe-76d8-4fbf-b3cd-8a0e447332b3'	System	21 Sep 2020 20:13:50
User entered 'No (N)'	System	21 Sep 2020 20:13:50

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-21T15:13:48', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7aedaabe-76d8-4fbf-b3cd-8a0e447332b3'	System	21 Sep 2020 20:13:50
User entered '21 Sep 2020 15:13'	System	21 Sep 2020 20:13:50

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 6'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-22T15:49:35', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '1d289f75-b370-4209-be8f-580863e7922a'	System	22 Sep 2020 20:49:57
User entered 'Yes (Y)'	System	22 Sep 2020 20:49:57

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-22T15:49:42', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '1d289f75-b370-4209-be8f-580863e7922a' User entered '97.7'	System	22 Sep 2020 20:49:57
	System	22 Sep 2020 20:49:57

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-22T15:49:46', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '1d289f75-b370-4209-be8f-580863e7922a'	System	22 Sep 2020 20:49:57
User entered 'No (N)'	System	22 Sep 2020 20:49:57

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-22T15:49:50', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '1d289f75-b370-4209-be8f-580863e7922a'	System	22 Sep 2020 20:49:57
User entered '22 Sep 2020 15:49'	System	22 Sep 2020 20:49:57

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 7'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-23T23:26:31', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'c171bf62-fccc-4934-b6c8-ac43c4b4a21c'	System	24 Sep 2020 04:26:51
User entered 'Yes (Y)'	System	24 Sep 2020 04:26:51

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-23T23:26:39', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'c171bf62-fccc-4934-b6c8-ac43c4b4a21c'	System	24 Sep 2020 04:26:51
User entered '97.5'	System	24 Sep 2020 04:26:51

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-23T23:26:43', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'c171bf62-fccc-4934-b6c8-ac43c4b4a21c'	System	24 Sep 2020 04:26:51
User entered 'No (N)'	System	24 Sep 2020 04:26:51

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-23T23:26:48', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'c171bf62-fccc-4934-b6c8-ac43c4b4a21c'	System	24 Sep 2020 04:26:51
User entered '23 Sep 2020 23:26'	System	24 Sep 2020 04:26:51

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T10:54:43', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '807e3f9e-70b8-4f00-9de5-7670b826375f'	System	17 Sep 2020 15:55:12
User entered 'None (1)'	System	17 Sep 2020 15:55:12

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T10:54:46', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '807e3f9e-70b8-4f00-9de5-7670b826375f'	System	17 Sep 2020 15:55:12
User entered 'No (N)'	System	17 Sep 2020 15:55:12

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T10:54:51', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '807e3f9e-70b8-4f00-9de5-7670b826375f'	System	17 Sep 2020 15:55:12
User entered 'No (N)'	System	17 Sep 2020 15:55:12

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T10:54:58', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '807e3f9e-70b8-4f00-9de5-7670b826375f'	System	17 Sep 2020 15:55:12
User entered 'None (1)'	System	17 Sep 2020 15:55:12

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T10:55:03', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '807e3f9e-70b8-4f00-9de5-7670b826375f'	System	17 Sep 2020 15:55:12
User entered '17 Sep 2020 10:55'	System	17 Sep 2020 15:55:12

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '17 Sep 2020 10:40'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '17 Sep 2020 13:10'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T15:56:27', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'e3e8b126-161e-45f9-b14c-aa211a2864c7'	System	17 Sep 2020 20:56:52
User entered 'None (1)'	System	17 Sep 2020 20:56:52

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T15:56:31', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'e3e8b126-161e-45f9-b14c-aa211a2864c7'	System	17 Sep 2020 20:56:52
User entered 'No (N)'	System	17 Sep 2020 20:56:52

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T15:56:34', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'e3e8b126-161e-45f9-b14c-aa211a2864c7'	System	17 Sep 2020 20:56:52
User entered 'No (N)'	System	17 Sep 2020 20:56:52

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T15:56:39', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'e3e8b126-161e-45f9-b14c-aa211a2864c7'	System	17 Sep 2020 20:56:52
User entered 'None (1)'	System	17 Sep 2020 20:56:52

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T15:56:49', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'e3e8b126-161e-45f9-b14c-aa211a2864c7'	System	17 Sep 2020 20:56:52
User entered '17 Sep 2020 15:56'	System	17 Sep 2020 20:56:52

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '17 Sep 2020 14:05'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 2'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-18T12:32:25', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '09e4ad41-dbd3-4e13-8b98-510bec57e5b6'	System	18 Sep 2020 17:32:46
User entered 'None (1)'	System	18 Sep 2020 17:32:46

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-18T12:32:29', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '09e4ad41-dbd3-4e13-8b98-510bec57e5b6'	System	18 Sep 2020 17:32:46
User entered 'No (N)'	System	18 Sep 2020 17:32:46

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-18T12:32:35', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '09e4ad41-dbd3-4e13-8b98-510bec57e5b6'	System	18 Sep 2020 17:32:46
User entered 'No (N)'	System	18 Sep 2020 17:32:46

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-18T12:32:39', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '09e4ad41-dbd3-4e13-8b98-510bec57e5b6'	System	18 Sep 2020 17:32:46
User entered 'None (1)'	System	18 Sep 2020 17:32:46

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-18T12:32:43', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '09e4ad41-dbd3-4e13-8b98-510bec57e5b6'	System	18 Sep 2020 17:32:46
User entered '18 Sep 2020 12:32'	System	18 Sep 2020 17:32:46

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 3'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-19T18:51:38', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '9cc6e08e-11bd-469f-b477-6b4fcf81d99f'	System	19 Sep 2020 23:52:03
User entered 'None (1)'	System	19 Sep 2020 23:52:03

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-19T18:51:41', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '9cc6e08e-11bd-469f-b477-6b4fcf81d99f'	System	19 Sep 2020 23:52:03
User entered 'No (N)'	System	19 Sep 2020 23:52:03

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-19T18:51:44', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '9cc6e08e-11bd-469f-b477-6b4fcf81d99f'	System	19 Sep 2020 23:52:03
User entered 'No (N)'	System	19 Sep 2020 23:52:03

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-19T18:51:48', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '9cc6e08e-11bd-469f-b477-6b4fcf81d99f'	System	19 Sep 2020 23:52:03
User entered 'None (1)'	System	19 Sep 2020 23:52:03

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-19T18:51:59', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '9cc6e08e-11bd-469f-b477-6b4fcf81d99f'	System	19 Sep 2020 23:52:03
User entered '19 Sep 2020 18:51'	System	19 Sep 2020 23:52:03

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 4'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-20T12:20:33', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '582eed70-f53a-459a-a4dd-7750a16a2358'	System	20 Sep 2020 17:20:59
User entered 'None (1)'	System	20 Sep 2020 17:20:59

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-20T12:20:36', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '582eed70-f53a-459a-a4dd-7750a16a2358'	System	20 Sep 2020 17:20:59
User entered 'No (N)'	System	20 Sep 2020 17:20:59

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-20T12:20:40', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '582eed70-f53a-459a-a4dd-7750a16a2358'	System	20 Sep 2020 17:20:59
User entered 'No (N)'	System	20 Sep 2020 17:20:59

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-20T12:20:48', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '582eed70-f53a-459a-a4dd-7750a16a2358'	System	20 Sep 2020 17:20:59
User entered 'None (1)'	System	20 Sep 2020 17:20:59

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-20T12:20:54', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '582eed70-f53a-459a-a4dd-7750a16a2358'	System	20 Sep 2020 17:20:59
User entered '20 Sep 2020 12:20'	System	20 Sep 2020 17:20:59

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 5'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-21T15:14:00', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'f905bbfe-7c95-4c3e-8186-edc1e29ceb93'	System	21 Sep 2020 20:14:17
User entered 'None (1)'	System	21 Sep 2020 20:14:17

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-21T15:14:03', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'f905bbfe-7c95-4c3e-8186-edc1e29ceb93'	System	21 Sep 2020 20:14:17
User entered 'No (N)'	System	21 Sep 2020 20:14:17

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-21T15:14:06', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'f905bbfe-7c95-4c3e-8186-edc1e29ceb93'	System	21 Sep 2020 20:14:17
User entered 'No (N)'	System	21 Sep 2020 20:14:17

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-21T15:14:11', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'f905bbfe-7c95-4c3e-8186-edc1e29ceb93'	System	21 Sep 2020 20:14:17
User entered 'None (1)'	System	21 Sep 2020 20:14:17

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-21T15:14:13', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'f905bbfe-7c95-4c3e-8186-edc1e29ceb93'	System	21 Sep 2020 20:14:17
User entered '21 Sep 2020 15:14'	System	21 Sep 2020 20:14:17

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 6'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-22T15:49:57', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0daa84c1-7c8b-4785-a0a2-a1e8ca1e1d10'	System	22 Sep 2020 20:50:17
User entered 'None (1)'	System	22 Sep 2020 20:50:17

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-22T15:50:00', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0daa84c1-7c8b-4785-a0a2-a1e8ca1e1d10'	System	22 Sep 2020 20:50:17
User entered 'No (N)'	System	22 Sep 2020 20:50:17

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-22T15:50:03', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0daa84c1-7c8b-4785-a0a2-a1e8ca1e1d10'	System	22 Sep 2020 20:50:17
User entered 'No (N)'	System	22 Sep 2020 20:50:17

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-22T15:50:10', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0daa84c1-7c8b-4785-a0a2-a1e8ca1e1d10'	System	22 Sep 2020 20:50:17
User entered 'None (1)'	System	22 Sep 2020 20:50:17

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-22T15:50:14', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0daa84c1-7c8b-4785-a0a2-a1e8ca1e1d10'	System	22 Sep 2020 20:50:17
User entered '22 Sep 2020 15:50'	System	22 Sep 2020 20:50:17

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 7'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-23T23:26:54', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '6bdf6d54-fadb-4a41-8658-f77c6e6fef7a'	System	24 Sep 2020 04:27:08
User entered 'None (1)'	System	24 Sep 2020 04:27:08

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-23T23:26:58', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '6bdf6d54-fadb-4a41-8658-f77c6e6fef7a'	System	24 Sep 2020 04:27:08
User entered 'No (N)'	System	24 Sep 2020 04:27:08

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-23T23:27:01', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '6bdf6d54-fadb-4a41-8658-f77c6e6fef7a'	System	24 Sep 2020 04:27:08
User entered 'No (N)'	System	24 Sep 2020 04:27:08

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-23T23:27:04', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '6bdf6d54-fadb-4a41-8658-f77c6e6fef7a'	System	24 Sep 2020 04:27:08
User entered 'None (1)'	System	24 Sep 2020 04:27:08

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-23T23:27:07', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '6bdf6d54-fadb-4a41-8658-f77c6e6fef7a'	System	24 Sep 2020 04:27:08
User entered '23 Sep 2020 23:27'	System	24 Sep 2020 04:27:08

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T10:55:14', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'db91ac1c-7df0-48b5-858b-5ee9d82e7e5a'	System	17 Sep 2020 15:55:53
User entered 'None (0)'	System	17 Sep 2020 15:55:53

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T10:55:20', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'db91ac1c-7df0-48b5-858b-5ee9d82e7e5a'	System	17 Sep 2020 15:55:53
User entered 'None (0)'	System	17 Sep 2020 15:55:53

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T10:55:23', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'db91ac1c-7df0-48b5-858b-5ee9d82e7e5a'	System	17 Sep 2020 15:55:53
User entered 'None (0)'	System	17 Sep 2020 15:55:53

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T10:55:31', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'db91ac1c-7df0-48b5-858b-5ee9d82e7e5a'	System	17 Sep 2020 15:55:53
User entered 'None (0)'	System	17 Sep 2020 15:55:53

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T10:55:34', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'db91ac1c-7df0-48b5-858b-5ee9d82e7e5a'	System	17 Sep 2020 15:55:53
User entered 'None (0)'	System	17 Sep 2020 15:55:53

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T10:55:37', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'db91ac1c-7df0-48b5-858b-5ee9d82e7e5a'	System	17 Sep 2020 15:55:53
User entered 'None (0)'	System	17 Sep 2020 15:55:53

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T10:55:44', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'db91ac1c-7df0-48b5-858b-5ee9d82e7e5a'	System	17 Sep 2020 15:55:53
User entered 'No (N)'	System	17 Sep 2020 15:55:53

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T10:55:47', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'db91ac1c-7df0-48b5-858b-5ee9d82e7e5a'	System	17 Sep 2020 15:55:53
User entered '17 Sep 2020 10:55'	System	17 Sep 2020 15:55:53

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '17 Sep 2020 10:40'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '17 Sep 2020 13:10'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T15:56:55', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0afc5583-8140-4bcf-a50f-a768482f777c'	System	17 Sep 2020 20:57:23
User entered 'None (0)'	System	17 Sep 2020 20:57:23

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T15:56:57', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0afc5583-8140-4bcf-a50f-a768482f777c'	System	17 Sep 2020 20:57:23
User entered 'None (0)'	System	17 Sep 2020 20:57:23

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T15:57:02', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0afc5583-8140-4bcf-a50f-a768482f777c'	System	17 Sep 2020 20:57:23
User entered 'None (0)'	System	17 Sep 2020 20:57:23

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T15:57:04', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0afc5583-8140-4bcf-a50f-a768482f777c'	System	17 Sep 2020 20:57:23
User entered 'None (0)'	System	17 Sep 2020 20:57:23

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T15:57:08', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0afc5583-8140-4bcf-a50f-a768482f777c'	System	17 Sep 2020 20:57:23
User entered 'None (0)'	System	17 Sep 2020 20:57:23

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T15:57:11', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0afc5583-8140-4bcf-a50f-a768482f777c'	System	17 Sep 2020 20:57:23
User entered 'None (0)'	System	17 Sep 2020 20:57:23

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T15:57:14', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0afc5583-8140-4bcf-a50f-a768482f777c'	System	17 Sep 2020 20:57:23
User entered 'No (N)'	System	17 Sep 2020 20:57:23

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-17T15:57:19', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0afc5583-8140-4bcf-a50f-a768482f777c'	System	17 Sep 2020 20:57:23
User entered '17 Sep 2020 15:57'	System	17 Sep 2020 20:57:23

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '17 Sep 2020 14:05'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 2'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-18T12:32:48', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '11ec2efb-8412-4d63-a8f0-cc2aaf8ccaca'	System	18 Sep 2020 17:33:17
User entered 'None (0)'	System	18 Sep 2020 17:33:17

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-18T12:32:53', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '11ec2efb-8412-4d63-a8f0-cc2aaf8ccaca'	System	18 Sep 2020 17:33:17
User entered 'None (0)'	System	18 Sep 2020 17:33:17

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-18T12:32:57', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '11ec2efb-8412-4d63-a8f0-cc2aaf8ccaca'	System	18 Sep 2020 17:33:17
User entered 'None (0)'	System	18 Sep 2020 17:33:17

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-18T12:33:00', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '11ec2efb-8412-4d63-a8f0-cc2aaf8ccaca'	System	18 Sep 2020 17:33:17
User entered 'None (0)'	System	18 Sep 2020 17:33:17

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-18T12:33:03', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '11ec2efb-8412-4d63-a8f0-cc2aaf8ccaca'	System	18 Sep 2020 17:33:17
User entered 'None (0)'	System	18 Sep 2020 17:33:17

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-18T12:33:06', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '11ec2efb-8412-4d63-a8f0-cc2aaf8ccaca'	System	18 Sep 2020 17:33:17
User entered 'None (0)'	System	18 Sep 2020 17:33:17

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-18T12:33:11', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '11ec2efb-8412-4d63-a8f0-cc2aaf8ccaca'	System	18 Sep 2020 17:33:17
User entered 'No (N)'	System	18 Sep 2020 17:33:17

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-18T12:33:15', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '11ec2efb-8412-4d63-a8f0-cc2aaf8ccaca'	System	18 Sep 2020 17:33:17
User entered '18 Sep 2020 12:33'	System	18 Sep 2020 17:33:17

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 3'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-19T18:52:07', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '080c329f-4df0-4fcd-80c7-dd7d03cfc5df'	System	19 Sep 2020 23:52:43
User entered 'None (0)'	System	19 Sep 2020 23:52:43

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-19T18:52:09', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '080c329f-4df0-4fcd-80c7-dd7d03cfc5df'	System	19 Sep 2020 23:52:43
User entered 'None (0)'	System	19 Sep 2020 23:52:43

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-19T18:52:12', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '080c329f-4df0-4fcd-80c7-dd7d03cfc5df'	System	19 Sep 2020 23:52:43
User entered 'None (0)'	System	19 Sep 2020 23:52:43

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-19T18:52:14', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '080c329f-4df0-4fcd-80c7-dd7d03cfc5df'	System	19 Sep 2020 23:52:43
User entered 'None (0)'	System	19 Sep 2020 23:52:43

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-19T18:52:18', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '080c329f-4df0-4fcd-80c7-dd7d03cfc5df'	System	19 Sep 2020 23:52:43
User entered 'None (0)'	System	19 Sep 2020 23:52:43

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-19T18:52:29', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '080c329f-4df0-4fcd-80c7-dd7d03cfc5df'	System	19 Sep 2020 23:52:43
User entered 'None (0)'	System	19 Sep 2020 23:52:43

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-19T18:52:34', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '080c329f-4df0-4fcd-80c7-dd7d03cfc5df'	System	19 Sep 2020 23:52:43
User entered 'No (N)'	System	19 Sep 2020 23:52:43

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-19T18:52:41', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '080c329f-4df0-4fcd-80c7-dd7d03cfc5df'	System	19 Sep 2020 23:52:43
User entered '19 Sep 2020 18:52'	System	19 Sep 2020 23:52:43

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 4'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-20T12:21:02', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '80111f79-0ef5-4fba-92cc-d0422bea0738'	System	20 Sep 2020 17:21:31
User entered 'None (0)'	System	20 Sep 2020 17:21:31

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-20T12:21:07', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '80111f79-0ef5-4fba-92cc-d0422bea0738'	System	20 Sep 2020 17:21:31
User entered 'None (0)'	System	20 Sep 2020 17:21:31

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-20T12:21:09', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '80111f79-0ef5-4fba-92cc-d0422bea0738'	System	20 Sep 2020 17:21:31
User entered 'None (0)'	System	20 Sep 2020 17:21:31

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-20T12:21:13', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '80111f79-0ef5-4fba-92cc-d0422bea0738'	System	20 Sep 2020 17:21:31
User entered 'None (0)'	System	20 Sep 2020 17:21:31

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-20T12:21:16', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '80111f79-0ef5-4fba-92cc-d0422bea0738'	System	20 Sep 2020 17:21:31
User entered 'None (0)'	System	20 Sep 2020 17:21:31

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-20T12:21:19', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '80111f79-0ef5-4fba-92cc-d0422bea0738'	System	20 Sep 2020 17:21:31
User entered 'None (0)'	System	20 Sep 2020 17:21:31

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-20T12:21:23', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '80111f79-0ef5-4fba-92cc-d0422bea0738'	System	20 Sep 2020 17:21:31
User entered 'No (N)'	System	20 Sep 2020 17:21:31

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-20T12:21:27', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '80111f79-0ef5-4fba-92cc-d0422bea0738'	System	20 Sep 2020 17:21:31
User entered '20 Sep 2020 12:21'	System	20 Sep 2020 17:21:31

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 5'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-21T15:14:19', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '6eab25da-17c8-4732-b0b5-eb252cf8894b'	System	21 Sep 2020 20:15:07
User entered 'None (0)'	System	21 Sep 2020 20:15:07

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-21T15:14:22', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '6eab25da-17c8-4732-b0b5-eb252cf8894b'	System	21 Sep 2020 20:15:07
User entered 'None (0)'	System	21 Sep 2020 20:15:07

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-21T15:14:25', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '6eab25da-17c8-4732-b0b5-eb252cf8894b'	System	21 Sep 2020 20:15:07
User entered 'None (0)'	System	21 Sep 2020 20:15:07

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-21T15:14:29', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '6eab25da-17c8-4732-b0b5-eb252cf8894b'	System	21 Sep 2020 20:15:07
User entered 'None (0)'	System	21 Sep 2020 20:15:07

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-21T15:14:39', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '6eab25da-17c8-4732-b0b5-eb252cf8894b'	System	21 Sep 2020 20:15:07
User entered 'None (0)'	System	21 Sep 2020 20:15:07

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-21T15:14:41', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '6eab25da-17c8-4732-b0b5-eb252cf8894b'	System	21 Sep 2020 20:15:07
User entered 'None (0)'	System	21 Sep 2020 20:15:07

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-21T15:14:49', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '6eab25da-17c8-4732-b0b5-eb252cf8894b'	System	21 Sep 2020 20:15:07
User entered 'No (N)'	System	21 Sep 2020 20:15:07

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-21T15:15:04', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '6eab25da-17c8-4732-b0b5-eb252cf8894b'	System	21 Sep 2020 20:15:07
User entered '21 Sep 2020 15:15'	System	21 Sep 2020 20:15:07

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 6'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-22T15:50:19', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'fd9f0c4b-9a82-4f93-a029-445ccf768198'	System	22 Sep 2020 20:51:00
User entered 'None (0)'	System	22 Sep 2020 20:51:00

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-22T15:50:22', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'fd9f0c4b-9a82-4f93-a029-445ccf768198'	System	22 Sep 2020 20:51:00
User entered 'None (0)'	System	22 Sep 2020 20:51:00

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-22T15:50:24', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'fd9f0c4b-9a82-4f93-a029-445ccf768198'	System	22 Sep 2020 20:51:00
User entered 'None (0)'	System	22 Sep 2020 20:51:00

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-22T15:50:27', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'fd9f0c4b-9a82-4f93-a029-445ccf768198'	System	22 Sep 2020 20:51:00
User entered 'None (0)'	System	22 Sep 2020 20:51:00

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-22T15:50:29', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'fd9f0c4b-9a82-4f93-a029-445ccf768198'	System	22 Sep 2020 20:51:00
User entered 'None (0)'	System	22 Sep 2020 20:51:00

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-22T15:50:32', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'fd9f0c4b-9a82-4f93-a029-445ccf768198'	System	22 Sep 2020 20:51:00
User entered 'None (0)'	System	22 Sep 2020 20:51:00

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-22T15:50:53', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'fd9f0c4b-9a82-4f93-a029-445ccf768198'	System	22 Sep 2020 20:51:00
User entered 'No (N)'	System	22 Sep 2020 20:51:00

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-22T15:50:57', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'fd9f0c4b-9a82-4f93-a029-445ccf768198'	System	22 Sep 2020 20:51:00
User entered '22 Sep 2020 15:50'	System	22 Sep 2020 20:51:00

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	17 Sep 2020 15:36:09
User entered 'Day 7'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-23T23:27:12', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '9de0055e-4e92-4dde-b96b-4e56f0570cec'	System	24 Sep 2020 04:27:50
User entered 'None (0)'	System	24 Sep 2020 04:27:50

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-23T23:27:15', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '9de0055e-4e92-4dde-b96b-4e56f0570cec'	System	24 Sep 2020 04:27:50
User entered 'None (0)'	System	24 Sep 2020 04:27:50

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-23T23:27:19', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '9de0055e-4e92-4dde-b96b-4e56f0570cec'	System	24 Sep 2020 04:27:50
User entered 'None (0)'	System	24 Sep 2020 04:27:50

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-23T23:27:22', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '9de0055e-4e92-4dde-b96b-4e56f0570cec'	System	24 Sep 2020 04:27:50
User entered 'None (0)'	System	24 Sep 2020 04:27:50

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-23T23:27:26', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '9de0055e-4e92-4dde-b96b-4e56f0570cec'	System	24 Sep 2020 04:27:50
User entered 'None (0)'	System	24 Sep 2020 04:27:50

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-23T23:27:29', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '9de0055e-4e92-4dde-b96b-4e56f0570cec'	System	24 Sep 2020 04:27:50
User entered 'None (0)'	System	24 Sep 2020 04:27:50

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-23T23:27:33', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '9de0055e-4e92-4dde-b96b-4e56f0570cec'	System	24 Sep 2020 04:27:50
User entered 'No (N)'	System	24 Sep 2020 04:27:50

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-09-23T23:27:45', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '9de0055e-4e92-4dde-b96b-4e56f0570cec'	System	24 Sep 2020 04:27:50
User entered '23 Sep 2020 23:27'	System	24 Sep 2020 04:27:50

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 15:36:09

US3442024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:42:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 15:36:09

US3442024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 16:25:14

US3442024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 16:25:14

US3442024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 16:25:14

US3442024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 16:25:14

US3442024

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 16:25:20

US3442024

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'I'	System	25 Sep 2020 16:25:20

US3442024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:50:52

US3442024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:50:52

US3442024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:50:52

US3442024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:50:52

US3442024

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:50:58

US3442024

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'I'	System	08 Oct 2020 19:50:58

US3442024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:51:11

US3442024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:51:11

US3442024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:51:11

US3442024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:51:11

US3442024

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:51:17

US3442024

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'I'	System	08 Oct 2020 19:51:17

US3442024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:21:56

US3442024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:21:56

US3442024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[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 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:21:56

US3442024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered 'VISIT3'	System	16 Oct 2020 15:21:56

US3442024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:22:29

US3442024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:22:29

US3442024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:22:29

US3442024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered empty.	System	16 Oct 2020 15:22:29

US3442024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:22:29

US3442024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:22:29

US3442024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:22:29

US3442024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:22:29

US3442024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered empty.	System	16 Oct 2020 15:22:29

US3442024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:22:29

US3442024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered empty.	System	16 Oct 2020 15:22:29

US3442024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:22:29

US3442024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered empty.	System	16 Oct 2020 15:22:29

US3442024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:22:29

US3442024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered empty.	System	16 Oct 2020 15:22:29

US3442024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08

US3442024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08

US3442024

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:22:55

US3442024

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:22:55

US3442024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:22:42

US3442024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:22:42

US3442024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '09:34'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:22:42

US3442024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered '16 Oct 2020 09:34'	System	16 Oct 2020 15:22:42

US3442024

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:22:48

US3442024

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:10:08
User entered '1'	System	16 Oct 2020 15:22:48

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 64'	System	18 Aug 2020 17:43:15

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Have you been exposed to someone with 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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Please 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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Please 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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Please 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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36
Data entry locked.	System	18 Aug 2020 17:43:15
User entered '18 Oct 2020 00:01'	System	18 Aug 2020 17:43:15

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36
Data entry locked.	System	18 Aug 2020 17:43:15
User entered '22 Oct 2020 23:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 71'	System	18 Aug 2020 17:43:15

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Have you been exposed to someone with 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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Please 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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Please 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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Please 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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36
Data entry locked.	System	18 Aug 2020 17:43:15
User entered '25 Oct 2020 00:01'	System	18 Aug 2020 17:43:15

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36
Data entry locked.	System	18 Aug 2020 17:43:15
User entered '29 Oct 2020 23:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 78'	System	18 Aug 2020 17:43:15

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Have you been exposed to someone with 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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Please 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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Please 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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Please 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 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36
Data entry locked.	System	18 Aug 2020 17:43:15
User entered '01 Nov 2020 00:01'	System	18 Aug 2020 17:43:15

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:14:36
Data entry locked.	System	18 Aug 2020 17:43:15
User entered '05 Nov 2020 23:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered 'Day 92'	System	18 Aug 2020 17:43:15

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-11-15T04:43:59', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '1fcd17ab-31f2-4a73-8b4b-fa2a749eabf4'	System	15 Nov 2020 10:44:18
User entered 'No (N)'	System	15 Nov 2020 10:44:18

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Have you been exposed to someone with 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 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-11-15T04:44:04', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '1fcd17ab-31f2-4a73-8b4b-fa2a749eabf4'	System	15 Nov 2020 10:44:18
User entered 'No (N)'	System	15 Nov 2020 10:44:18

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-11-15T04:44:12', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '1fcd17ab-31f2-4a73-8b4b-fa2a749eabf4'	System	15 Nov 2020 10:44:18
User entered '15 Nov 2020 04:44:12'	System	15 Nov 2020 10:44:18

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered '15 Nov 2020 00:01'	System	18 Aug 2020 17:43:15

US3442024

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:13:53
Data entry locked.	System	18 Aug 2020 17:43:15
User entered '19 Nov 2020 23:59'	System	18 Aug 2020 17:43:15

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2020-12-07T09:47:23', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '6ee9249f-1839-4bbf-9a24-1b3231ec41ca'	System	07 Dec 2020 15:47:42
User entered 'No (N)'	System	07 Dec 2020 15:47:42

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2020-12-07T09:47:28', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '6ee9249f-1839-4bbf-9a24-1b3231ec41ca'	System	07 Dec 2020 15:47:42
User entered 'No (N)'	System	07 Dec 2020 15:47:42

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-12-07T09:47:38', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '6ee9249f-1839-4bbf-9a24-1b3231ec41ca' User entered '07 Dec 2020 09:47:38'	System	07 Dec 2020 15:47:42

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 07:54:24
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'per subject, this was answered after surgery took place. There was not an additional AE' (Site from DM).	Tisha Davis (b) (4) (b) (4)	06 Mar 2021 16:14:59
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:08:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-12-14T10:57:56', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7b06540e-c742-4646-abe4-8d4625223ab7'	System	14 Dec 2020 16:58:52
User entered 'Yes (Y)'	System	14 Dec 2020 16:58:52

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2020-12-14T10:58:02', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7b06540e-c742-4646-abe4-8d4625223ab7'	System	14 Dec 2020 16:58:52
User entered 'No (N)'	System	14 Dec 2020 16:58:52

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2020-12-14T10:58:20', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7b06540e-c742-4646-abe4-8d4625223ab7'	System	14 Dec 2020 16:58:52
User entered 'No (N)'	System	14 Dec 2020 16:58:52

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2020-12-14T10:58:28', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7b06540e-c742-4646-abe4-8d4625223ab7'	System	14 Dec 2020 16:58:52
User entered 'Yes (Y)'	System	14 Dec 2020 16:58:52

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Please 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 (bbcee7f8b398bd7c)', Time: '2020-12-14T10:58:36', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7b06540e-c742-4646-abe4-8d4625223ab7'	System	14 Dec 2020 16:58:52
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Dec 2020 16:58:52

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-12-14T10:58:41', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '7b06540e-c742-4646-abe4-8d4625223ab7' User entered '14 Dec 2020 10:58:41'	System	14 Dec 2020 16:58:52
	System	14 Dec 2020 16:58:52

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2020-12-21T16:15:43', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0680cf53-d175-4722-b809-f842de2b274f'	System	21 Dec 2020 22:16:27
User entered 'No (N)'	System	21 Dec 2020 22:16:27

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2020-12-21T16:16:01', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0680cf53-d175-4722-b809-f842de2b274f'	System	21 Dec 2020 22:16:27
User entered 'Yes (Y)'	System	21 Dec 2020 22:16:27

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please 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 (bbcee7f8b398bd7c)', Time: '2020-12-21T16:16:09', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0680cf53-d175-4722-b809-f842de2b274f'	System	21 Dec 2020 22:16:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Dec 2020 22:16:27

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-12-21T16:16:15', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0680cf53-d175-4722-b809-f842de2b274f' User entered '21 Dec 2020 16:16:15'	System	21 Dec 2020 22:16:27
	System	21 Dec 2020 22:16:27

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2020-12-24T00:04:40', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0d682a22-aa4e-4478-8c0c-90f1d0462628'	System	24 Dec 2020 06:05:15
User entered 'No (N)'	System	24 Dec 2020 06:05:15

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2020-12-24T00:04:48', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0d682a22-aa4e-4478-8c0c-90f1d0462628'	System	24 Dec 2020 06:05:15
User entered 'Yes (Y)'	System	24 Dec 2020 06:05:15

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Please 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 (bbcee7f8b398bd7c)', Time: '2020-12-24T00:04:58', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0d682a22-aa4e-4478-8c0c-90f1d0462628'	System	24 Dec 2020 06:05:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Dec 2020 06:05:15

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-12-24T00:05:05', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0d682a22-aa4e-4478-8c0c-90f1d0462628'	System	24 Dec 2020 06:05:15
User entered '24 Dec 2020 00:05:05'	System	24 Dec 2020 06:05:15

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2020-12-31T12:39:06', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '1ed83f83-5587-45de-aa20-a87b4b186577'	System	31 Dec 2020 18:39:20
User entered 'No (N)'	System	31 Dec 2020 18:39:20

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2020-12-31T12:39:13', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '1ed83f83-5587-45de-aa20-a87b4b186577'	System	31 Dec 2020 18:39:20
User entered 'No (N)'	System	31 Dec 2020 18:39:20

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2020-12-31T12:39:17', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '1ed83f83-5587-45de-aa20-a87b4b186577'	System	31 Dec 2020 18:39:20
User entered '31 Dec 2020 12:39:17'	System	31 Dec 2020 18:39:20

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2021-01-07T00:02:53', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'd94bd002-923b-4534-880f-68bfa118460f'	System	07 Jan 2021 06:03:08
User entered 'No (N)'	System	07 Jan 2021 06:03:08

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2021-01-07T00:03:02', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'd94bd002-923b-4534-880f-68bfa118460f'	System	07 Jan 2021 06:03:08
User entered 'No (N)'	System	07 Jan 2021 06:03:08

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2021-01-07T00:03:06', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'd94bd002-923b-4534-880f-68bfa118460f' User entered '07 Jan 2021 00:03:06'	System	07 Jan 2021 06:03:08
	System	07 Jan 2021 06:03:08

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2021-01-14T00:32:24', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'd0c6461d-534e-4094-a879-35d52cb841da'	System	14 Jan 2021 06:32:31
User entered 'No (N)'	System	14 Jan 2021 06:32:31

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2021-01-14T00:32:27', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'd0c6461d-534e-4094-a879-35d52cb841da'	System	14 Jan 2021 06:32:31
User entered 'No (N)'	System	14 Jan 2021 06:32:31

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2021-01-14T00:32:31', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'd0c6461d-534e-4094-a879-35d52cb841da' User entered '14 Jan 2021 00:32:31'	System	14 Jan 2021 06:32:31

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2021-01-21T10:11:09', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'da4eecdf-2ef1-4cc1-83f3-d99fdefd6938'	System	21 Jan 2021 16:11:28
User entered 'No (N)'	System	21 Jan 2021 16:11:28

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2021-01-21T10:11:15', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'da4eecdf-2ef1-4cc1-83f3-d99fdefd6938'	System	21 Jan 2021 16:11:28
User entered 'No (N)'	System	21 Jan 2021 16:11:28

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2021-01-21T10:11:26', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'da4eecdf-2ef1-4cc1-83f3-d99fdefd6938' User entered '21 Jan 2021 10:11:26'	System	21 Jan 2021 16:11:28
	System	21 Jan 2021 16:11:28

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2021-02-01T19:10:15', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '959c3a09-41c0-4736-9532-3d9f8788fa89'	System	02 Feb 2021 01:10:29
User entered 'No (N)'	System	02 Feb 2021 01:10:29

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2021-02-01T19:10:22', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '959c3a09-41c0-4736-9532-3d9f8788fa89'	System	02 Feb 2021 01:10:29
User entered 'No (N)'	System	02 Feb 2021 01:10:29

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2021-02-01T19:10:26', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '959c3a09-41c0-4736-9532-3d9f8788fa89'	System	02 Feb 2021 01:10:29
User entered '01 Feb 2021 19:10:26'	System	02 Feb 2021 01:10:29

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2021-02-08T13:37:42', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '66d6ecea-e53a-4215-a623-9cd83769e326'	System	08 Feb 2021 19:37:58
User entered 'No (N)'	System	08 Feb 2021 19:37:58

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2021-02-08T13:37:48', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '66d6ecea-e53a-4215-a623-9cd83769e326'	System	08 Feb 2021 19:37:58
User entered 'No (N)'	System	08 Feb 2021 19:37:58

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2021-02-08T13:37:52', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '66d6ecea-e53a-4215-a623-9cd83769e326'	System	08 Feb 2021 19:37:58
User entered '08 Feb 2021 13:37:52'	System	08 Feb 2021 19:37:58

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2021-02-18T00:02:24', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '157a5d59-d01d-4f6b-9443-6d27a75b06e8'	System	18 Feb 2021 06:02:39
User entered 'No (N)'	System	18 Feb 2021 06:02:39

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2021-02-18T00:02:29', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '157a5d59-d01d-4f6b-9443-6d27a75b06e8'	System	18 Feb 2021 06:02:39
User entered 'No (N)'	System	18 Feb 2021 06:02:39

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2021-02-18T00:02:34', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '157a5d59-d01d-4f6b-9443-6d27a75b06e8'	System	18 Feb 2021 06:02:39
User entered '18 Feb 2021 00:02:34'	System	18 Feb 2021 06:02:39

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2021-02-25T02:33:39', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '2f3ec47b-6008-4da4-a70e-261af9f1be4e'	System	25 Feb 2021 08:33:55
User entered 'No (N)'	System	25 Feb 2021 08:33:55

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2021-02-25T02:33:45', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '2f3ec47b-6008-4da4-a70e-261af9f1be4e'	System	25 Feb 2021 08:33:55
User entered 'No (N)'	System	25 Feb 2021 08:33:55

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2021-02-25T02:33:50', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '2f3ec47b-6008-4da4-a70e-261af9f1be4e'	System	25 Feb 2021 08:33:55
User entered '25 Feb 2021 02:33:50'	System	25 Feb 2021 08:33:55

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2021-03-15T17:33:35', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0abfd329-9b42-4db4-a546-fbdf5ab5dedf'	System	15 Mar 2021 22:34:01
User entered 'No (N)'	System	15 Mar 2021 22:34:01

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2021-03-15T17:33:40', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0abfd329-9b42-4db4-a546-fbdf5ab5dedf'	System	15 Mar 2021 22:34:01
User entered 'No (N)'	System	15 Mar 2021 22:34:01

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2021-03-15T17:33:45', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '0abfd329-9b42-4db4-a546-fbdf5ab5dedf' User entered '15 Mar 2021 17:33:45'	System	15 Mar 2021 22:34:01

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2021-03-22T09:50:41', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'ebe1c04c-dfdd-4b3c-b961-780d4b24ab92'	System	22 Mar 2021 14:50:57
User entered 'No (N)'	System	22 Mar 2021 14:50:57

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2021-03-22T09:50:47', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'ebe1c04c-dfdd-4b3c-b961-780d4b24ab92'	System	22 Mar 2021 14:50:57
User entered 'No (N)'	System	22 Mar 2021 14:50:57

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2021-03-22T09:50:53', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'ebe1c04c-dfdd-4b3c-b961-780d4b24ab92'	System	22 Mar 2021 14:50:57
User entered '22 Mar 2021 09:50:53'	System	22 Mar 2021 14:50:57

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2021-03-25T00:52:51', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '664c6915-0520-44ec-b1ee-9e81217b1566'	System	25 Mar 2021 05:53:06
User entered 'No (N)'	System	25 Mar 2021 05:53:06

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2021-03-25T00:52:57', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '664c6915-0520-44ec-b1ee-9e81217b1566'	System	25 Mar 2021 05:53:06
User entered 'No (N)'	System	25 Mar 2021 05:53:06

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2021-03-25T00:53:01', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '664c6915-0520-44ec-b1ee-9e81217b1566'	System	25 Mar 2021 05:53:06
User entered '25 Mar 2021 00:53:01'	System	25 Mar 2021 05:53:06

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2021-04-01T03:23:22', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '09bdc65e-8914-411d-8b29-1070e0bd7fe7'	System	01 Apr 2021 08:23:34
User entered 'No (N)'	System	01 Apr 2021 08:23:34

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2021-04-01T03:23:27', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '09bdc65e-8914-411d-8b29-1070e0bd7fe7'	System	01 Apr 2021 08:23:34
User entered 'No (N)'	System	01 Apr 2021 08:23:34

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2021-04-01T03:23:31', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '09bdc65e-8914-411d-8b29-1070e0bd7fe7'	System	01 Apr 2021 08:23:34
User entered '01 Apr 2021 03:23:31'	System	01 Apr 2021 08:23:34

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2021-04-08T06:57:17', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '16e8a7bf-9b48-456b-8a24-a1b961bf06fd'	System	08 Apr 2021 11:57:27
User entered 'No (N)'	System	08 Apr 2021 11:57:27

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2021-04-08T06:57:19', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '16e8a7bf-9b48-456b-8a24-a1b961bf06fd'	System	08 Apr 2021 11:57:27
User entered 'No (N)'	System	08 Apr 2021 11:57:27

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2021-04-08T06:57:22', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '16e8a7bf-9b48-456b-8a24-a1b961bf06fd' User entered '08 Apr 2021 06:57:22'	System	08 Apr 2021 11:57:27
	System	08 Apr 2021 11:57:27

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2021-04-15T00:07:01', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '77f5a6c8-7c20-464f-ad85-690cb928cc79'	System	15 Apr 2021 05:07:18
User entered 'No (N)'	System	15 Apr 2021 05:07:18

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2021-04-15T00:07:07', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '77f5a6c8-7c20-464f-ad85-690cb928cc79'	System	15 Apr 2021 05:07:18
User entered 'No (N)'	System	15 Apr 2021 05:07:18

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2021-04-15T00:07:14', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '77f5a6c8-7c20-464f-ad85-690cb928cc79'	System	15 Apr 2021 05:07:18
User entered '15 Apr 2021 00:07:14'	System	15 Apr 2021 05:07:18

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2021-04-26T17:44:18', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'fbe9b3c5-9e9f-4507-812a-485a6ea8c93c'	System	26 Apr 2021 22:44:31
User entered 'No (N)'	System	26 Apr 2021 22:44:31

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2021-04-26T17:44:23', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'fbe9b3c5-9e9f-4507-812a-485a6ea8c93c'	System	26 Apr 2021 22:44:31
User entered 'No (N)'	System	26 Apr 2021 22:44:31

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2021-04-26T17:44:27', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: 'fbe9b3c5-9e9f-4507-812a-485a6ea8c93c'	System	26 Apr 2021 22:44:31
User entered '26 Apr 2021 17:44:27'	System	26 Apr 2021 22:44:31

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[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 (bbcee7f8b398bd7c)', Time: '2021-04-29T00:01:37', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '782ffc6f-f2fc-474e-bcd5-6686f8a4a1fc'	System	29 Apr 2021 05:01:56
User entered 'No (N)'	System	29 Apr 2021 05:01:56

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

Have you been exposed to someone with 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 (bbcee7f8b398bd7c)', Time: '2021-04-29T00:01:40', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '782ffc6f-f2fc-474e-bcd5-6686f8a4a1fc'	System	29 Apr 2021 05:01:56
User entered 'No (N)'	System	29 Apr 2021 05:01:56

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2021-04-29T00:01:44', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '782ffc6f-f2fc-474e-bcd5-6686f8a4a1fc' User entered '29 Apr 2021 00:01:44'	System	29 Apr 2021 05:01:56
	System	29 Apr 2021 05:01:56

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 22:14:36

US3442024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:14:36
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 22:14:36

US3442024

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:42:11

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 11:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2021-03-15T17:33:56', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '8057e08b-8d1d-40e1-acb5-09d7d182c2c7'	System	15 Mar 2021 22:34:08
User entered 'No (N)'	System	15 Mar 2021 22:34:08

US3442024

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:42:11

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:32:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bbcee7f8b398bd7c)', Time: '2021-03-15T17:34:00', User OID: 'PatientReportedOutcome (US3442024)', ODM File OID: '8057e08b-8d1d-40e1-acb5-09d7d182c2c7'	System	15 Mar 2021 22:34:08
User entered '15 Mar 2021 17:34:00'	System	15 Mar 2021 22:34:08

US3442024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:53
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 20:47:16

US3442024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:53
User entered '9 Nov 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 20:47:16

US3442024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 20:47:16

US3442024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:53
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 20:47:16

US3442024

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	09 Nov 2020 20:47:24

US3442024

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:09:25
User entered 'I'	System	09 Nov 2020 20:47:24

US3442024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:30:27
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Dec 2020 00:48:37

US3442024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:30:27
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '2 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Dec 2020 00:48:37

US3442024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:30:27
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Dec 2020 00:48:37

US3442024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:30:27
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	03 Dec 2020 00:48:37

US3442024

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:30:27
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:53
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Dec 2020 00:48:48

US3442024

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:30:27
User entered 'I'	System	03 Dec 2020 00:48:48

US3442024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:30:27
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 02:09:38

US3442024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:30:27
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '12 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 02:09:38

US3442024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:30:27
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 02:09:38

US3442024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:30:27
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 02:09:38

US3442024

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:30:27
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	13 Jan 2021 02:09:45

US3442024

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:30:27
User entered '1'	System	13 Jan 2021 02:09:45

US3442024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:30:27
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:51:35
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 21:40:27

US3442024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:30:27
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:51:35
User entered '12 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 21:40:27

US3442024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:30:27
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:51:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 21:40:27

US3442024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:30:27
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:51:35
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 21:40:27

US3442024

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:30:27
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:51:35
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Feb 2021 21:40:37

US3442024

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:30:27
User entered 'I'	System	22 Feb 2021 21:40:37

US3442024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:46:34

US3442024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered '22 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:46:34

US3442024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[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 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered 'Clinic (Clinic)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:46:34

US3442024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'VISIT4'	System	22 Mar 2021 21:46:34

US3442024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered 'No (N)'	(b) (4) John Villegas (b) (4)	30 Mar 2021 18:30:46
	(b) (4)	

US3442024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) John Villegas (b) (4) (b) (4)	30 Mar 2021 18:30:46

US3442024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) John Villegas (b) (4) (b) (4)	30 Mar 2021 18:30:46

US3442024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	30 Mar 2021 18:30:46

US3442024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) John Villegas (b) (4) (b) (4)	30 Mar 2021 18:30:46

US3442024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) John Villegas (b) (4) (b) (4)	30 Mar 2021 18:30:46

US3442024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) John Villegas (b) (4) (b) (4)	30 Mar 2021 18:30:46

US3442024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) John Villegas (b) (4) (b) (4)	30 Mar 2021 18:30:46

US3442024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	30 Mar 2021 18:30:46

US3442024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) John Villegas (b) (4)	30 Mar 2021 18:30:46
	(b) (4)	

US3442024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	30 Mar 2021 18:30:46

US3442024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) John Villegas (b) (4) (b) (4)	30 Mar 2021 18:30:46

US3442024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	30 Mar 2021 18:30:46

US3442024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) John Villegas (b) (4) (b) (4)	30 Mar 2021 18:30:46

US3442024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered empty.	System	30 Mar 2021 18:30:46

US3442024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14

US3442024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14

US3442024

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:47:34

US3442024

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:47:34

US3442024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:48:03

US3442024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered '22 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:48:03

US3442024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered '13:41'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:48:03

US3442024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered '22 Mar 2021 13:41'	System	22 Mar 2021 21:48:03

US3442024

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:48:12

US3442024

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:14
User entered 'I'	System	22 Mar 2021 21:48:12

US3442024

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Apr 2021 19:43:41

US3442024

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered '12 Apr 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Apr 2021 19:43:41

US3442024

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Apr 2021 19:43:41

US3442024

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	12 Apr 2021 19:43:41

US3442024

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	12 Apr 2021 19:43:47

US3442024

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 19:43:47

US3442024

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

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:04:30

US3442024

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

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '14 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:04:30

US3442024

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

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Clinic (Clinic)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:04:30

US3442024

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

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'UNBLND_DECIDE'	System	16 Jan 2021 02:04:30

US3442024

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:11

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '14 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:04:58

US3442024

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:11

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:35:12

US3442024

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:11

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:04:58

US3442024

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:11

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:35:12

US3442024

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:11

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '14 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:04:58

US3442024

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Placebo (Placebo)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:04:58

US3442024

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:11

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 02:35:27
User entered 'Placebo (Placebo)'	Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:04:58

US3442024

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:11

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 02:35:27
User entered 'Placebo (Placebo)'	Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:04:58

US3442024

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:11

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:04:58

US3442024

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:11

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered '1'	System	16 Jan 2021 02:04:58

US3442024

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

Form: Unblinding

Generated On: 09 Jun 2021 17:42:11

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered '1'	System	16 Jan 2021 02:04:58

US3442024

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered empty.	System	16 Jan 2021 02:06:15
DataPoint set to visible.	System	16 Jan 2021 02:04:58

US3442024

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered empty.	System	16 Jan 2021 02:06:15
DataPoint set to visible.	System	16 Jan 2021 02:04:58

US3442024

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User accepted default value 'Pre-Dose (PREDOSE)'	Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '14 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '10:15'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered '14 Jan 2021 10:15'	System	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '98.4' F	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Oral (Oral)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '74'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'bpm'	System	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '16'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'breaths/min'	System	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '130'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'mmHg'	System	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '78'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'mmHg'	System	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:06:15

US3442024

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:42:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered empty.	System	16 Jan 2021 02:06:15
DataPoint set to visible.	System	16 Jan 2021 02:04:58

US3442024

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User accepted default value 'Post-Dose (POSTDOSE)'	Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:07:13

US3442024

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:07:13

US3442024

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '14 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:07:13

US3442024

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '11:40'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:07:13

US3442024

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered '14 Jan 2021 11:40'	System	16 Jan 2021 02:07:13

US3442024

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '98.0' F	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:07:13

US3442024

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Oral (Oral)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:07:13

US3442024

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:07:13

US3442024

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '60'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:07:13

US3442024

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'bpm'	System	16 Jan 2021 02:07:13

US3442024

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '14'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:07:13

US3442024

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'breaths/min'	System	16 Jan 2021 02:07:13

US3442024

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '118'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:07:13

US3442024

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'mmHg'	System	16 Jan 2021 02:07:13

US3442024

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '73'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:07:13

US3442024

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'mmHg'	System	16 Jan 2021 02:07:13

US3442024

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:07:28

US3442024

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '14 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:07:28

US3442024

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

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:08:11

US3442024

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

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:08:11

US3442024

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

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:08:11

US3442024

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

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'mRNA-1273'	System	16 Jan 2021 02:08:11
DataPoint set to visible.	System	16 Jan 2021 02:04:58

US3442024

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

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '14 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:08:11

US3442024

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

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '11:06'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:08:11

US3442024

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

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered '14 Jan 2021 11:06'	System	16 Jan 2021 02:08:11

US3442024

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

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:08:11

US3442024

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

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'ONCE'	System	16 Jan 2021 02:08:11

US3442024

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

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'INTRAMUSCULAR'	System	16 Jan 2021 02:08:11

US3442024

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:08:52

US3442024

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '14 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:08:52

US3442024

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '10:20'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:08:52

US3442024

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered '14 Jan 2021 10:20'	System	16 Jan 2021 02:08:52

US3442024

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:42:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:09:16

US3442024

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:42:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '14 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:09:16

US3442024

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:42:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '10:18'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:09:16

US3442024

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:42:11

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered '14 Jan 2021 10:18'	System	16 Jan 2021 02:09:16

US3442024

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

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	16 Jan 2021 02:09:27

US3442024

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

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered '1'	System	16 Jan 2021 02:09:27

US3442024

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:57:03

US3442024

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '21 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:57:03

US3442024

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:57:03

US3442024

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:57:03

US3442024

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	23 Jan 2021 01:57:11

US3442024

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'I'	System	23 Jan 2021 01:57:11

US3442024

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'I'	System	23 Jan 2021 01:57:11
DataPoint set to visible.	System	23 Jan 2021 01:57:11

US3442024

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:11:53

US3442024

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	22 Mar 2021 21:55:33
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	22 Mar 2021 21:55:33
User entered '23 Feb 2021' reason for change: Data Entry Error	Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:55:33
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	22 Mar 2021 21:54:06
Signature has been broken.	Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:54:06
User entered '22 Mar 2021' reason for change: Data Entry Error	Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:54:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '23 Feb 2021'	Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:11:53

US3442024

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered 'Clinic (Clinic)'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:11:53

US3442024

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'OLD29'	System	24 Feb 2021 01:11:53

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User accepted default value 'Pre-Dose (PREDOSE)'	Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:13:05

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:13:05

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Mar 2021 21:55:33
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Mar 2021 21:54:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '23 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:13:05

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '13:07'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:13:05

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered '23 Feb 2021 13:07'	System	24 Feb 2021 01:13:05

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '98.9' F	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:13:05

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered 'Oral (Oral)'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:13:05

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:13:05

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '78'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:13:05

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'bpm'	System	24 Feb 2021 01:13:05

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '15'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:13:05

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'breaths/min'	System	24 Feb 2021 01:13:05

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '116'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:13:05

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'mmHg'	System	24 Feb 2021 01:13:05

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 09:38:12
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per Sub - 1' (Site from System).	Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:13:49
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		24 Feb 2021 01:13:05
User entered '58'	Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:13:05

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:42:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'mmHg'	System	24 Feb 2021 01:13:05

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User accepted default value 'Post-Dose (POSTDOSE)'	Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:16:25

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:16:25

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Mar 2021 21:55:33
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Mar 2021 21:54:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '23 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:16:25

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '14:20'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:16:25

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered '23 Feb 2021 14:20'	System	24 Feb 2021 01:16:25

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '98.2' F	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:16:25

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered 'Oral (Oral)'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:16:25

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:16:25

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '72'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:16:25

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'bpm'	System	24 Feb 2021 01:16:25

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '12'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:16:25

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'breaths/min'	System	24 Feb 2021 01:16:25

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '108'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:16:25

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'mmHg'	System	24 Feb 2021 01:16:25

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '68'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:16:25

US3442024

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:42:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'mmHg'	System	24 Feb 2021 01:16:25

US3442024

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:16:58

US3442024

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Mar 2021 21:55:33
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Mar 2021 21:54:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '23 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:16:58

US3442024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:17:51

US3442024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:17:51

US3442024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:17:51

US3442024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'mRNA-1273'	System	24 Feb 2021 01:17:51
DataPoint set to visible.	System	23 Jan 2021 01:57:11

US3442024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	22 Mar 2021 21:55:33
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	22 Mar 2021 21:55:33
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	22 Mar 2021 21:54:06
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '23 Feb 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:17:51

US3442024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '13:43'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:17:51

US3442024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered '23 Feb 2021 13:43'	System	24 Feb 2021 01:17:51

US3442024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered 'Left Arm (LEFT ARM)'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:17:51

US3442024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'ONCE'	System	24 Feb 2021 01:17:51

US3442024

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'INTRAMUSCULAR'	System	24 Feb 2021 01:17:51

US3442024

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	24 Feb 2021 01:17:59

US3442024

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered '1'	System	24 Feb 2021 01:17:59

US3442024

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:57:16

US3442024

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '2 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:57:16

US3442024

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:57:16

US3442024

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:42:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:57:16

US3442024

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	03 Mar 2021 01:57:24

US3442024

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:42:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'I'	System	03 Mar 2021 01:57:24

US3442024

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:50:12

US3442024

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered '22 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:50:12

US3442024

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered 'Clinic (Clinic)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:50:12

US3442024

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:42:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'OLD57'	System	22 Mar 2021 21:50:12

US3442024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:52:10

US3442024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered '22 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:52:10

US3442024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered '13:33'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:52:10

US3442024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered '22 Mar 2021 13:33'	System	22 Mar 2021 21:52:10

US3442024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered '99.5' F	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:52:10

US3442024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered 'Oral (Oral)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:52:10

US3442024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:52:10

US3442024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered '63'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:52:10

US3442024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'bpm'	System	22 Mar 2021 21:52:10

US3442024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered '16'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:52:10

US3442024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'breaths/min'	System	22 Mar 2021 21:52:10

US3442024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered '123'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:52:10

US3442024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'mmHg'	System	22 Mar 2021 21:52:10

US3442024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered '65'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:52:10

US3442024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered 'mmHg'	System	22 Mar 2021 21:52:10

US3442024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47

US3442024

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:42:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47

US3442024

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:52:18

US3442024

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:42:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:52:18

US3442024

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:52:52

US3442024

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered '22 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	22 Mar 2021 21:52:52

US3442024

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered '13:41' reason for change: Data Entry Error	(b) (4)	22 Mar 2021 21:53:22
User entered '13:33'	Oluwatosin Akingbala	22 Mar 2021 21:52:52
	(b) (4)	

US3442024

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:42:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:05:47
User entered '22 Mar 2021 13:41'	System	22 Mar 2021 21:53:22
User entered '22 Mar 2021 13:33'	System	22 Mar 2021 21:52:52

US3442024

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:42:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:20:40
DataPoint Verified.		21 Apr 2021 19:25:27
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Tisha Davis (b) (4)	14 Dec 2020 16:37:02
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	02 Sep 2020 21:06:16

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:02:54
Reviewed for Safety.		15 Dec 2020 14:43:43
User entered		15 Dec 2020 14:43:37
'USA-US017-2020-mRNA-1273-P301000007'		
User entered 'New'		15 Dec 2020 14:43:37

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:02:56
User closed query 'PV Query: Thank you for confirming this was a worsening of osteoarthritis. Please update event term to include worsening of right hip osteoarthritis, and remove right high replacement from event term as the procedure is considered treatment and should not be included in event term.' (Site from Safety).		01 Mar 2021 19:44:48
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Feb 2021 20:23:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Feb 2021 20:23:30
Data point term sent to Coder	System	28 Feb 2021 20:22:37
Query 'PV Query: Thank you for confirming this was a worsening of osteoarthritis. Please update event term to include worsening of right hip osteoarthritis, and remove right high replacement from event term as the procedure is considered treatment and should not be included in event term.' answered with 'updated' (Site from Safety).	Alma Guel (b) (4)	28 Feb 2021 20:21:52
Coding entries removed.	Alma Guel (b) (4)	28 Feb 2021 20:21:42
User entered 'worsening of RIGHT HIP OSTEOARTHRITIS' reason for change: Data Entry Error	Alma Guel (b) (4)	28 Feb 2021 20:21:42
User opened query 'PV Query: Thank you for confirming this was a worsening of osteoarthritis. Please update event term to include worsening of right hip osteoarthritis, and remove right high replacement from event term as the procedure is considered treatment and should not be included in event term.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 04:31:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Feb 2021 15:48:26

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 15:48:26
User closed query 'PV Query: Please update the event term to the underlying condition. If this is a worsening of the underlying condition, please document as such.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 14:56:38
Query 'PV Query: Please update the event term to the underlying condition. If this is a worsening of the underlying condition, please document as such.' answered with 'updated per query' (Site from Safety).	Tisha Davis (b) (4)	28 Jan 2021 17:56:17
Data point term sent to Coder	System	28 Jan 2021 17:56:01
DataPoint Un-verified.	Tisha Davis (b) (4)	28 Jan 2021 17:55:55
Coding entries removed.	Tisha Davis (b) (4)	28 Jan 2021 17:55:55
User entered 'RIGHT HIP REPLACEMENT (secondary to osteoarthritis of the right hip)' reason for change: Data Entry Error	Tisha Davis (b) (4)	28 Jan 2021 17:55:55
User opened query 'PV Query: Please update the event term to the underlying condition. If this is a worsening of the underlying condition, please document as such.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 13:46:28
User closed query 'PV Query: Please update the event term to the underlying condition. If this is a worsening of the underlying condition, please document as such.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 16:05:59
User closed query 'Per CDM: Per sponsor review, please consider adding this procedure to concomitant procedure CRF.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 15:44:32
Query 'PV Query: Please update the event term to the underlying condition. If this is a worsening of the underlying condition, please document as such.' answered with 'medical records have been re-requested. AE will be updated once received.' (Site from Safety).	Tisha Davis (b) (4)	26 Jan 2021 16:02:40
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:24:58
Query 'Per CDM: Per sponsor review, please consider adding this procedure to concomitant procedure CRF.' answered with 'done' (Site from DM).		25 Jan 2021 15:05:32

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthropathy, LLT: Hip arthropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Jan 2021 14:41:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Jan 2021 14:41:40
User opened query 'Per CDM: Per sponsor review, please consider adding this procedure to concomitant procedure CRF. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 14:14:08
User opened query 'PV Query: Please update the event term to the underlying condition. If this is a worsening of the underlying condition, please document as such. ' (Site from Safety).		22 Dec 2020 13:52:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 16:51:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 16:51:55
Data point term sent to Coder	System	14 Dec 2020 16:51:05
User entered 'Right Hip Replacement'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:25:03
User entered 'Yes (Y)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:25:05
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:25:08
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:25:09
User entered '07 Dec 2020'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:25:54
User entered empty.	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:25:56
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:25:57
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	14 Dec 2020 16:53:10
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	14 Dec 2020 16:53:10
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	14 Dec 2020 16:50:48
User entered '08 Dec 2020'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:25:59
User entered empty.	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:26:00
User entered 'Grade 3/Severe (Grade 3/Severe)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:26:01
User entered 'Yes (Y)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:26:04
User entered '0'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:26:08
User entered '0'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:26:09
User entered 'I'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:26:11
User entered '07 Dec 2020'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:26:12
User entered '08 Dec 2020'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:03:07
DataPoint Un-verified.		25 Jan 2021 21:26:15
DataPoint Verified.		25 Jan 2021 21:26:14
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:03:08
User entered empty.	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:03:09
User entered '0'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:03:11
User entered '0'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:18:13
User entered '0'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:26:20
User entered 'Not Related (NOT RELATED)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:26:21
User entered 'Not Related (NOT RELATED)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:26:22
User entered 'Not Applicable (NOT APPLICABLE)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

None

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:26:27
User entered '0'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:26:25
User entered 'I'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:18:15
User closed query 'Per DM CLR: Please review if ConProc should be added as there is a CP that matches this AE indication within the timeframe. Update as appropriate. Otherwise, provide clarification.' (Site from DM).		24 Mar 2021 07:25:43
Query 'Per DM CLR: Please review if ConProc should be added as there is a CP that matches this AE indication within the timeframe. Update as appropriate. Otherwise, provide clarification.' answered with 'updated.' (Site from DM).	Oluwatosin Akingbala (b) (4)	24 Mar 2021 00:19:29
DataPoint Un-verified.	Oluwatosin Akingbala (b) (4)	24 Mar 2021 00:19:18
User entered '1' reason for change: Per Query Resolution	Oluwatosin Akingbala (b) (4)	24 Mar 2021 00:19:18
User opened query 'Per DM CLR: Please review if ConProc should be added as there is a CP that matches this AE indication within the timeframe. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 18:31:27
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:26:28
User entered '0'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:26:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:53:10
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:26:40
User entered empty.	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:21:40
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. Please leave query open until information is available.' (Site from Safety).		15 Mar 2021 14:28:54
User closed query 'PV Query: Please provide any relevant diagnostic imaging results. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 14:28:51
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. Please leave query open until information is available.' answered with 'No COVID -19 testing was performed.' (Site from Safety).	Tisha Davis (b) (4) (b) (4)	12 Mar 2021 19:09:15
Query 'PV Query: Please provide any relevant diagnostic imaging results. Please leave query open until information is available.' answered with 'no other diagnostic imaging was performed.' (Site from Safety).	Tisha Davis (b) (4) (b) (4)	12 Mar 2021 19:08:50
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 18:44:04
User opened query 'PV Query: Please provide any relevant diagnostic imaging results. Please leave query open until information is available.' (Site from Safety).		08 Mar 2021 18:43:57
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).		08 Mar 2021 17:22:13

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant diagnostic imaging results.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 17:22:08
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 'additional medical records requested..' (Site from Safety).	Tisha Davis (b) (4) (b) (4)	06 Mar 2021 16:00:05
Query 'PV Query: Please provide any relevant diagnostic imaging results.' answered with 'additional medical records requested 3/6/2021' (Site from Safety).	Tisha Davis (b) (4) (b) (4)	06 Mar 2021 15:59:43
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)	12 Feb 2021 04:30:18
User opened query 'PV Query: Please provide any relevant diagnostic imaging results.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 04:29:57
User closed query 'PV Query: Please confirm if the worsening of osteoarthritis occurred prior to study? Was this considered a preplanned surgery prior to start of study? If so, please consider deleting event from EDC as it does not meet criteria for reporting.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 15:22:53
Query 'PV Query: Please confirm if the worsening of osteoarthritis occurred prior to study? Was this considered a preplanned surgery prior to start of study? If so, please consider deleting event from EDC as it does not meet criteria for reporting.' answered with 'confirmed that this was a worsening of Osteoarthritis' (Site from Safety).	Tisha Davis (b) (4) (b) (4)	04 Feb 2021 17:17:19
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)	29 Jan 2021 14:56:56
User closed query 'PV Query: Please provide any relevant diagnostic imaging results.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 14:56:51

PRODUCTION RELEASE (v12.003
EAB) (1725)

2038 of 2793

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 14:56:45
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 'will update pending medical records' (Site from Safety).	Tisha Davis (b) (4) (b) (4)	28 Jan 2021 17:57:12
Query 'PV Query: Please provide any relevant diagnostic imaging results.' answered with 'will update pending medical records' (Site from Safety).	Tisha Davis (b) (4) (b) (4)	28 Jan 2021 17:57:01
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'will update pending medical records' (Site from Safety).	Tisha Davis (b) (4) (b) (4)	28 Jan 2021 17:56:55
User opened query 'PV Query: Please confirm if the worsening of osteoarthritis occurred prior to study? Was this considered a preplanned surgery prior to start of study? If so, please consider deleting event from EDC as it does not meet criteria for reporting.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 13:46:38
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).		28 Jan 2021 13:46:17
User opened query 'PV Query: Please provide any relevant diagnostic imaging results.' (Site from Safety).		28 Jan 2021 13:46:09

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 13:46:01
User closed query 'PV Query: Please confirm if the worsening of osteoarthritis occurred prior to study? Was this considered a preplanned surgery prior to start of study? If so, please consider deleting event from EDC as it does not meet criteria for reporting. ' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 16:06:08
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)	27 Jan 2021 16:06:06
User closed query 'PV Query: Please provide any relevant diagnostic imaging results. ' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 16:06:04
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 16:06:02
Query 'PV Query: Please confirm if the worsening of osteoarthritis occurred prior to study? Was this considered a preplanned surgery prior to start of study? If so, please consider deleting event from EDC as it does not meet criteria for reporting. ' answered with 'medical records have been re-requested. AE will be updated once received.' (Site from Safety).	Tisha Davis (b) (4) (b) (4)	26 Jan 2021 16:03:14

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Narrative](#)

Audit	User	Time (GMT)
Query '. PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'medical records have been re-requested. AE will be updated once received.' (Site from Safety).	Tisha Davis (b) (4)	26 Jan 2021 16:03:05
Query 'PV Query: Please provide any relevant diagnostic imaging results. ' answered with 'medical records have been re-requested. AE will be updated once received.' (Site from Safety).	Tisha Davis (b) (4)	26 Jan 2021 16:02:55
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'medical records have been re-requested. AE will be updated once received.' (Site from Safety).	Tisha Davis (b) (4)	26 Jan 2021 16:02:49
User opened query 'PV Query: Please confirm if the worsening of osteoarthritis occurred prior to study? Was this considered a preplanned surgery prior to start of study? If so, please consider deleting event from EDC as it does not meet criteria for reporting. ' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 13:52:20
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).		22 Dec 2020 13:51:53
User opened query 'PV Query: Please provide any relevant diagnostic imaging results. ' (Site from Safety).		22 Dec 2020 13:50:57
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).		22 Dec 2020 13:50:37

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Dec 2020 16:55:27
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	14 Dec 2020 16:55:27
User entered 'Patient has had Osteoarthritis in right hip since 2015, per patient pcp, patient had right hip replacement.' reason for change: Data Entry Error	Tisha Davis (b) (4)	14 Dec 2020 16:55:27
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Dec 2020 16:50:48
User entered empty.	Tisha Davis (b) (4)	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
User entered '0'	System	14 Dec 2020 16:50:48

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:26:53
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative hip pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 18:40:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 18:40:47
Data point term sent to Coder	System	14 Dec 2020 17:02:18
User entered 'Pain right hip (due to right hip replacement)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:21:57
User closed query 'Source doesn't match. Per source this is not a MAAE. Please refer to source to update the field. ' (Site from CRA).		22 Feb 2021 06:04:28
Query 'Source doesn't match. Per source this is not a MAAE. Please refer to source to update the field. ' answered with 'data updated per query' (Site from CRA).	Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:30:11
User opened query 'Source doesn't match. Per source this is not a MAAE. Please refer to source to update the field. ' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 21:27:36
DataPoint Un-verified.		25 Jan 2021 21:26:58
DataPoint Verified.		25 Jan 2021 21:26:55
User entered 'Yes (Y)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:27:39
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:27:40
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:27:43
User entered '07 Dec 2020'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:27:45
User entered empty.	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User entered empty.	System	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 00:16:13
User closed query 'Per source end date is 28Feb2021. Please change the response.' (Site from CRA).		12 Apr 2021 00:16:08
Query 'Per source end date is 28Feb2021. Please change the response.' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	05 Apr 2021 20:07:30
User entered 'No (N)' reason for change: Data Entry Error	Alma Guel (b) (4)	05 Apr 2021 20:07:14
User opened query 'Per source end date is 28Feb2021. Please change the response.' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 19:22:35
DataPoint Un-verified.		05 Apr 2021 19:22:07
DataPoint Verified.		25 Jan 2021 21:27:46
User entered 'Yes (Y)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 00:16:15
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	05 Apr 2021 20:07:22
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	05 Apr 2021 20:07:22
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	05 Apr 2021 20:07:14
DataPoint Un-verified.	Alma Guel (b) (4)	05 Apr 2021 20:07:14
User entered '28 Feb 2021' reason for change: Data Entry Error	Alma Guel (b) (4)	05 Apr 2021 20:07:14
DataPoint Verified.	(b) (4), (b) (6)	25 Jan 2021 21:27:51
User entered empty.	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:27:53
User entered empty.	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User entered empty.	System	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:27:57
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:27:58
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:12
User entered '0'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:13
User entered '0'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:15
User entered '0'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:16
User entered empty.	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:18
User entered empty.	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:19
User entered empty.	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:21
User entered empty.	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:22
User entered '0'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:23
User entered '0'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:25
User entered '0'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:26
User entered 'Not Related (NOT RELATED)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:27
User entered 'Not Related (NOT RELATED)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:29
User entered 'Not Applicable (NOT APPLICABLE)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:30
User entered '0'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'data updated per query' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 15:11:29
DataPoint Verified.	Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:30:49
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). User entered '1'	(b) (4), (b) (6)	25 Jan 2021 21:28:33 13 Jan 2021 04:37:43
	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:35
User entered '0'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 00:16:31
User closed query 'This event is resolved per source. please change the entry' (Site from CRA).		12 Apr 2021 00:16:28
Query 'This event is resolved per source. please change the entry' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	05 Apr 2021 20:07:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Alma Guel (b) (4)	05 Apr 2021 20:07:22
Data Entry Error		
User opened query 'This event is resolved per source. please change the entry' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 19:23:39
DataPoint Un-verified.		05 Apr 2021 19:22:45
DataPoint Verified.		25 Jan 2021 21:28:36
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:37
User entered empty.	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:39
User entered empty.	Tisha Davis (b) (4) (b) (4)	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User entered '0'	System	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04
User entered '1'	System	14 Dec 2020 17:02:01

US3442024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:04

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:20:40
User closed query 'Lactated Ringers solution with 100ml continuous IV drip on 07Dec20 for indication IV Drip surgery. Please add this to the logline' (Site from CRA).		28 Apr 2021 19:11:32
Query 'Lactated Ringers solution with 100ml continuous IV drip on 07Dec20 for indication IV Drip surgery. Please add this to the logline' answered with 'this data has been added' (Site from CRA).	Alma Guel (b) (4)	24 Apr 2021 16:36:58
User opened query 'Lactated Ringers solution with 100ml continuous IV drip on 07Dec20 for indication IV Drip surgery. Please add this to the logline' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 21:44:10
Query 'Lactated Ringers solution with 100ml continuous IV drip on 07Dec20 for indication IV Drip surgery. ' canceled (Site from CRA).		23 Apr 2021 21:43:55
User opened query 'Lactated Ringers solution with 100ml continuous IV drip on 07Dec20 for indication IV Drip surgery. ' (Site from CRA).		23 Apr 2021 21:43:49
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 19:24:06
User closed query 'Subject had a hip replacement surgery on 07Dec2020. Please refer to medical records obtained on 14Dec2020 to update the con meds. ' (Site from CRA).		05 Apr 2021 19:23:59
Query 'Subject had a hip replacement surgery on 07Dec2020. Please refer to medical records obtained on 14Dec2020 to update the con meds. ' answered with 'updated per query' (Site from CRA).	Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:36:33
User opened query 'Subject had a hip replacement surgery on 07Dec2020. Please refer to medical records obtained on 14Dec2020 to update the con meds. ' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 21:33:07
User entered 'Yes (Y)'		19 Aug 2020 23:08:06

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:49
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:27:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DETEMIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:26:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:26:19
Data point term sent to Coder	System	19 Apr 2021 19:51:26
DataPoint Un-verified.	Alma Guel (b) (4)	19 Apr 2021 19:51:01
Coding entries removed.	Alma Guel (b) (4)	19 Apr 2021 19:51:01
Signature has been broken.	Alma Guel (b) (4)	19 Apr 2021 19:51:01
User entered 'DETEMIR' reason for change: Data Entry Error	Alma Guel (b) (4)	19 Apr 2021 19:51:01
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:40:30
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:11:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DETEMIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 09:48:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 09:48:34
Data point term sent to Coder	System	21 Aug 2020 22:56:59
User closed query 'For coding purpose, please check spelling and update this term in accordance with your answer.' (Site from System).	System	21 Aug 2020 22:56:31

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

Name of Medication

Audit	User	Time (GMT)
Query 'For coding purpose, please check spelling and update this term in accordance with your answer.' answered with 'INFORMATION CORRECTED' (Site from System).	(b) (4), (b) (6)	21 Aug 2020 22:56:31
User entered 'INSULIN DETEMIR' reason for change: Data Entry Error		21 Aug 2020 22:56:17
Data point term sent to Coder	System	21 Aug 2020 22:55:58
User entered 'DETEMIR INSULIN' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 22:55:40
User opened query 'For coding purpose, please check spelling and update this term in accordance with your answer.' (Site from System).	Coder Import (b) (4)	21 Aug 2020 12:33:10
Data point term sent to Coder	System	19 Aug 2020 23:20:01
Data point term sent to Coder	System	19 Aug 2020 23:14:56
User entered 'debamir'	(b) (4), (b) (6)	19 Aug 2020 23:14:21

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:49
DataPoint Verified.		05 Apr 2021 19:40:33
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:14:21

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:49
DataPoint Verified.		05 Apr 2021 19:40:36
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'DM 2'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:14:21

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:49
DataPoint Verified.		19 Apr 2021 18:25:58
DataPoint Un-verified.		05 Apr 2021 19:41:13
DataPoint Verified.		05 Apr 2021 19:40:46
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '24'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:14:21

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:49
DataPoint Verified.		19 Apr 2021 18:26:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'IU (IU)' reason for change: Per Query Resolution	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:48:54
User entered 'Other (OTHER)'		19 Aug 2020 23:14:21

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:49
DataPoint Verified.		19 Apr 2021 18:26:05
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User closed query 'Per DM CLR: Please note, 'UNITS' is available in the listed options in 'Dose Unit - IU'. Please review and update eCRF as appropriate.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 12:16:05
Query 'Per DM CLR: Please note, 'UNITS' is available in the listed options in 'Dose Unit - IU'. Please review and update eCRF as appropriate.		08 Oct 2020 19:49:02
' answered with 'updated' (Site from DM).		
User entered empty; reason for change Per Query Resolution		08 Oct 2020 19:48:54
User opened query 'Per DM CLR: Please note, 'UNITS' is available in the listed options in 'Dose Unit - IU'. Please review and update eCRF as appropriate.		29 Sep 2020 07:58:42
' (Site from DM).		
User entered 'units'		19 Aug 2020 23:14:21

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:49
DataPoint Verified.		19 Apr 2021 18:26:21
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:14:21

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:49
DataPoint Verified.		19 Apr 2021 18:26:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:14:21

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:49
DataPoint Verified.		19 Apr 2021 18:26:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 23:19:28
User entered 'Intramuscular (INTRAMUSCULAR)'		19 Aug 2020 23:14:21

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:49
DataPoint Verified.		19 Apr 2021 18:26:27
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:14:21

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:26:31
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	20 Aug 2020 19:05:37
answered with 'corrected' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 23:20:12
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 23:19:28
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	19 Aug 2020 23:19:28
User entered 'un UNK 2008' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 23:19:28
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	19 Aug 2020 23:14:21
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 23:14:21

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:49
DataPoint Verified.		19 Apr 2021 18:26:33
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:14:21

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:49
DataPoint Verified.		23 Apr 2021 20:48:51
User closed query 'This has an end date as 07Dec2020 per source. Please change the response' (Site from CRA).		23 Apr 2021 20:48:50
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
Query 'This has an end date as 07Dec2020 per source. Please change the response' answered with 'updated . Thank you.' (Site from CRA).	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:18:35
Signature has been broken.	Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:18:12
User entered 'No (N)' reason for change: Per Query Resolution	Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:18:12
User opened query 'This has an end date as 07Dec2020 per source. Please change the response' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:34:26
DataPoint Un-verified.		21 Apr 2021 20:34:04
DataPoint Verified.		19 Apr 2021 18:26:36
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:14:21

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:49
DataPoint Verified.	(b) (4)	23 Apr 2021 20:48:53
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
DataPoint Un-verified.	(b) (4)	
	Oluwatosin Akingbala	21 Apr 2021 21:18:12
Signature has been broken.	(b) (4)	
	Oluwatosin Akingbala	21 Apr 2021 21:18:12
User entered '07 Dec 2020' reason for change: Per Query Resolution	(b) (4)	
DataPoint Verified.	Oluwatosin Akingbala	21 Apr 2021 21:18:12
	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	19 Apr 2021 18:26:38
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty; reason for change Data Entry Error	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 23:19:53
User entered ' 2008' (non-conformant).	(b) (4), (b) (6)	19 Aug 2020 23:19:53
		19 Aug 2020 23:14:21
		19 Aug 2020 23:14:21

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:49
DataPoint Verified.		19 Apr 2021 18:26:40
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:14:21

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:49
User entered '2'	System	19 Aug 2020 23:14:21

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:49
User entered '1'	System	19 Aug 2020 23:14:21

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:49
User entered '804 (804)'	System	19 Aug 2020 23:14:21

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:11

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:34:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
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)	25 Aug 2020 16:12:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 16:12:37
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	25 Aug 2020 16:11:57 25 Aug 2020 16:11:46
User entered 'METFORMIN' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 16:11:46
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)	20 Aug 2020 06:55:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 06:55:13
Data point term sent to Coder User entered 'Metaformin'	System (b) (4), (b) (6)	19 Aug 2020 23:16:57 19 Aug 2020 23:16:24

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:34:48
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:16:24

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:34:49
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'DM 2'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:16:24

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:34:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '500'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:16:24

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:34:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:16:24

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:34:54
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:16:24

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:34:55
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:16:24

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:34:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:16:24

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:34:59
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:16:24

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:35:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:16:24

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:35:04
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:05:57
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 23:20:53
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 23:16:24
User entered 'un UNK 1998'	(b) (4), (b) (6)	19 Aug 2020 23:16:24

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:35:07
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:16:24

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:35:40
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:16:24

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:35:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:16:24

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:35:46
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:16:24

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 23:16:24

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 23:16:24

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 23:16:24

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:00:40
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
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 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Nov 2020 09:09:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 09:09:31
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	05 Nov 2020 20:32:42 05 Nov 2020 20:31:44
User entered 'EMPAGLIFLOZIN' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 20:31:44
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 12:39:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 12:39:56
Data point term sent to Coder User entered 'Empagliflozin'	System (b) (4), (b) (6)	19 Aug 2020 23:18:00 19 Aug 2020 23:17:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:00:43
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:17:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:00:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'DM 2'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:17:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:00:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 06:56:12
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'confirmed with subject that the dosage is 12.5 mg' (Site from DM).		05 Nov 2020 20:37:47
User entered '12.5' reason for change: Data Entry Error		05 Nov 2020 20:37:25
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).		04 Nov 2020 09:51:22
User entered '12'		19 Aug 2020 23:17:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:00:50
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:17:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:00:54
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:17:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:00:55
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:17:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:00:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:17:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:00:59
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:17:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:01:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:17:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:01:05
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:06:02
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 23:21:10
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 23:17:26
User entered 'un UNK 2018'	(b) (4), (b) (6)	19 Aug 2020 23:17:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:01:06
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:17:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:01:17
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:17:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:01:18
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:17:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:01:20
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:17:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 23:17:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 23:17:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 23:17:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:11

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:02:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Aug 2020 06:57:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:57:15
Data point term sent to Coder	System	19 Aug 2020 23:19:00
User entered 'Glizipide'	(b) (4), (b) (6)	19 Aug 2020 23:18:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:02:06
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:18:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:02:10
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'DM 2'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:18:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:02:12
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '10'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:18:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:02:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:18:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:02:21
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:18:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:02:23
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:18:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:02:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:18:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:02:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:18:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:02:31
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:18:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:02:33
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:06:08
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 23:21:20
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 23:18:39
User entered 'un UNK 2012'	(b) (4), (b) (6)	19 Aug 2020 23:18:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:02:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:18:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:02:36
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:18:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:02:37
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:18:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:02:39
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:18:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 23:18:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 23:18:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 23:18:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:11

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:10:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: THIAZOLIDINEDIONES, PRODUCT: PIOGLITAZONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Aug 2020 06:32:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:32:23
Data point term sent to Coder	System	19 Aug 2020 23:23:05
User entered 'Pioglitazone'	(b) (4), (b) (6)	19 Aug 2020 23:22:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:10:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:22:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:10:27
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'DM 2'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:22:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:10:29
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '45'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:22:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:10:31
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:22:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:10:32
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:22:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:10:34
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:22:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:10:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:22:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:10:37
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:22:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:10:38
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:22:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:10:44
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:06:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 23:26:14
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 23:22:52
User entered 'un UNK 2016'	(b) (4), (b) (6)	19 Aug 2020 23:22:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:10:46
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:22:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:10:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:22:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:10:49
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:22:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:10:50
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:22:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 23:22:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 23:22:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 23:22:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:57
DataPoint Verified.		21 Apr 2021 20:36:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Aug 2020 23:25:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 23:25:06
Data point term sent to Coder	System	19 Aug 2020 23:24:06
User entered 'simvastatin'	(b) (4), (b) (6)	19 Aug 2020 23:23:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:57
DataPoint Verified.		21 Apr 2021 20:36:15
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:23:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:57
DataPoint Verified.		21 Apr 2021 20:36:17
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'high cholesterol'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:23:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:57
DataPoint Verified.		21 Apr 2021 20:36:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '20'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:23:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:57
DataPoint Verified.		21 Apr 2021 20:36:21
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:23:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:57
DataPoint Verified.		21 Apr 2021 20:36:22
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:23:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:57
DataPoint Verified.		21 Apr 2021 20:36:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:23:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:57
DataPoint Verified.		21 Apr 2021 20:36:25
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:23:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:57
DataPoint Verified.		21 Apr 2021 20:36:27
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:23:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:57
DataPoint Verified.		21 Apr 2021 20:36:28
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:23:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:57
DataPoint Verified.		21 Apr 2021 20:36:30
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	20 Aug 2020 19:06:19
answered with 'correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 23:25:25
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 23:23:51
User entered 'un UNK 2005'	(b) (4), (b) (6)	19 Aug 2020 23:23:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:57
DataPoint Verified.		21 Apr 2021 20:36:32
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:23:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:57
DataPoint Verified.		23 Apr 2021 20:49:16
User closed query 'Please change the response to 07Dec2020 per source' (Site from CRA).		23 Apr 2021 20:49:15
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
Query 'Please change the response to 07Dec2020 per source' answered with 'updated . Thank you.' (Site from CRA).	(b) (4)	
	Oluwatosin Akingbala	21 Apr 2021 21:20:09
Signature has been broken.	(b) (4)	
	Oluwatosin Akingbala	21 Apr 2021 21:19:58
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	21 Apr 2021 21:19:58
User opened query 'Please change the response to 07Dec2020 per source' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:36:56
DataPoint Un-verified.		21 Apr 2021 20:36:35
DataPoint Verified.		21 Apr 2021 20:36:33
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	19 Aug 2020 23:23:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:57
DataPoint Verified.		23 Apr 2021 20:49:18
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
Signature has been broken.	(b) (4) Oluwatosin Akingbala	21 Apr 2021 21:19:58
User entered '07 Dec 2020' reason for change: Per Query Resolution	(b) (4) Oluwatosin Akingbala	21 Apr 2021 21:19:58
User signature succeeded.	(b) (4) William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:23:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:57
DataPoint Verified.		23 Apr 2021 20:49:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:23:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:57
User entered '1'	System	19 Aug 2020 23:23:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:57
User entered '1'	System	19 Aug 2020 23:23:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:09:57
User entered '804 (804)'	System	19 Aug 2020 23:23:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:11

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:03:50
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	19 Aug 2020 23:27:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	19 Aug 2020 23:27:06
Data point term sent to Coder	System	19 Aug 2020 23:26:09
Data point term sent to Coder	System	19 Aug 2020 23:25:08
User entered 'Lisinopril'	(b) (4), (b) (6)	19 Aug 2020 23:24:44

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:03:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:24:44

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:03:53
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'hypertension' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:25:12
User entered 'high cholesterol'		19 Aug 2020 23:24:44

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:03:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '20'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:24:44

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:03:59
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:24:44

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:04:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:24:44

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:04:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:24:44

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:04:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:24:44

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:04:04
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:24:44

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:04:05
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:24:44

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:04:07
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:06:28
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 23:24:58
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 23:24:44
User entered 'un UNK 2005'	(b) (4), (b) (6)	19 Aug 2020 23:24:44

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:04:12
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:24:44

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:04:13
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:24:44

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:04:15
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:24:44

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:04:17
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:24:44

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 23:24:44

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 23:24:44

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 23:24:44

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:02
DataPoint Verified.		21 Apr 2021 20:42:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: NAPROXEN NA - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Aug 2020 06:50:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:50:12
Data point term sent to Coder	System	19 Aug 2020 23:30:13
User entered 'Naproxen na'	(b) (4), (b) (6)	19 Aug 2020 23:29:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:02
DataPoint Verified.		21 Apr 2021 20:42:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:29:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:02
DataPoint Verified.		21 Apr 2021 20:42:04
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
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) (4), (b) (6)	14 Oct 2020 12:16:15
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 'updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:49:58
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).		29 Sep 2020 08:01:38
User entered 'osteoarthritis'		19 Aug 2020 23:29:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:02
DataPoint Verified.		21 Apr 2021 20:42:06
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '440'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:29:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:02
DataPoint Verified.		21 Apr 2021 20:42:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:29:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:02
DataPoint Verified.		21 Apr 2021 20:42:09
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:29:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:02
DataPoint Verified.		21 Apr 2021 20:42:10
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:29:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:02
DataPoint Verified.		21 Apr 2021 20:42:12
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:29:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:02
DataPoint Verified.		21 Apr 2021 20:42:13
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:29:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:02
DataPoint Verified.		21 Apr 2021 20:42:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:29:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:02
DataPoint Verified.		21 Apr 2021 20:43:06
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:06:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	19 Aug 2020 23:29:27
answered with 'correct as entered' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 23:29:18
User entered 'un Feb 2019'	(b) (4), (b) (6)	19 Aug 2020 23:29:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:02
DataPoint Verified.		21 Apr 2021 20:43:09
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:29:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:02
DataPoint Verified.		21 Apr 2021 20:43:10
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
Signature has been broken.	(b) (4)	
	Oluwatosin Akingbala	24 Feb 2021 01:25:55
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Oluwatosin Akingbala	24 Feb 2021 01:25:55
	(b) (4)	
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 23:29:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:02
DataPoint Verified.		21 Apr 2021 20:43:11
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
Signature has been broken.	(b) (4)	
	Oluwatosin Akingbala	24 Feb 2021 01:25:55
	(b) (4)	
User entered '30 Jan 2021' reason for change: New Information	Oluwatosin Akingbala	24 Feb 2021 01:25:55
	(b) (4)	
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 23:29:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:02
DataPoint Verified.		21 Apr 2021 20:43:13
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:29:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:02
User entered empty.	System	19 Aug 2020 23:29:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:02
User entered empty.	System	19 Aug 2020 23:29:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:02
User entered empty.	System	19 Aug 2020 23:29:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:08
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:43:18
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User closed query 'Per DM CLR: This Con Med was added on after first dose of study vaccination. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM). Query 'Per DM CLR: This Con Med was added on after first dose of study vaccination. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' answered with 'no worsening/exacerbation. subject's PCP wanted to try new treatment due to subject's active lifestyle' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 06:58:26
User opened query 'Per DM CLR: This Con Med was added on after first dose of study vaccination. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 20:34:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	04 Nov 2020 09:51:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Sep 2020 17:06:41
Data point term sent to Coder	System	17 Sep 2020 17:05:42

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'meloxicam'	(b) (4), (b) (6)	17 Sep 2020 17:05:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:08
DataPoint Verified.		21 Apr 2021 20:43:31
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:05:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:08
DataPoint Verified.		21 Apr 2021 20:43:50
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'osteoarthritis'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:05:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:08
DataPoint Verified.		21 Apr 2021 20:43:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '15'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:05:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:08
DataPoint Verified.		21 Apr 2021 20:43:53
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:05:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:08
DataPoint Verified.		21 Apr 2021 20:43:55
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:05:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:08
DataPoint Verified.		21 Apr 2021 20:43:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:05:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:08
DataPoint Verified.		21 Apr 2021 20:43:59
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:05:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:08
DataPoint Verified.		21 Apr 2021 20:44:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:05:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:08
DataPoint Verified.		21 Apr 2021 20:44:02
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:05:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:08
DataPoint Verified.		21 Apr 2021 20:44:04
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:05:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:08
DataPoint Verified.		21 Apr 2021 20:44:05
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:05:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:08
DataPoint Verified.		23 Apr 2021 20:49:43
User closed query 'Not on-going. Please change the end date per source as 07Dec2020' (Site from CRA).		23 Apr 2021 20:49:41
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
Query 'Not on-going. Please change the end date per source as 07Dec2020' answered with 'updated .	(b) (4)	
Thank you.' (Site from CRA).	Oluwatosin Akingbala	21 Apr 2021 21:23:37
Signature has been broken.	(b) (4)	
User entered 'No (N)' reason for change: Per Query Resolution	Oluwatosin Akingbala	21 Apr 2021 21:23:32
User opened query 'Not on-going. Please change the end date per source as 07Dec2020' (Site from CRA).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	21 Apr 2021 20:44:34
User entered 'Yes (Y)'	William Seger (b) (4)	13 Feb 2021 00:11:17
	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 17:05:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:08
DataPoint Verified.		23 Apr 2021 20:49:44
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
Signature has been broken.	(b) (4) Oluwatosin Akingbala	21 Apr 2021 21:23:32
User entered '07 Dec 2020' reason for change: Per Query Resolution	(b) (4) Oluwatosin Akingbala	21 Apr 2021 21:23:32
User signature succeeded.	(b) (4) William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:05:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:08
DataPoint Verified.		23 Apr 2021 20:49:46
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:05:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:08
User entered empty.	System	17 Sep 2020 17:05:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:08
User entered empty.	System	17 Sep 2020 17:05:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:08
User entered empty.	System	17 Sep 2020 17:05:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:14
DataPoint Verified.		21 Apr 2021 20:44:40
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	25 Mar 2021 15:40:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 15:40:28
Data point term sent to Coder	System	25 Mar 2021 15:40:16
Coding entries removed.	(b) (4), (b) (6)	25 Mar 2021 15:39:43
Signature has been broken.		25 Mar 2021 15:39:43
User entered 'Acetaminophen' reason for change:		25 Mar 2021 15:39:43
Data Entry Error		
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: APAP - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	17 Sep 2020 17:07:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Sep 2020 17:07:36
Data point term sent to Coder	System	17 Sep 2020 17:06:43
User entered 'apap'	(b) (4), (b) (6)	17 Sep 2020 17:06:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:14
DataPoint Verified.		21 Apr 2021 20:44:41
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:06:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:14
DataPoint Verified.		21 Apr 2021 20:44:56
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'osteoarthritis'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:06:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:14
DataPoint Verified.		21 Apr 2021 20:45:06
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '500'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:06:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:14
DataPoint Verified.		21 Apr 2021 20:45:07
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:06:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:14
DataPoint Verified.		21 Apr 2021 20:45:09
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:06:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:14
DataPoint Verified.		21 Apr 2021 20:45:10
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:06:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:14
DataPoint Verified.		21 Apr 2021 20:45:11
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:06:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:14
DataPoint Verified.		21 Apr 2021 20:45:13
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:06:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:14
DataPoint Verified.		21 Apr 2021 20:45:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:06:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:14
DataPoint Verified.		21 Apr 2021 20:45:16
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:06:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:14
DataPoint Verified.		21 Apr 2021 20:45:18
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:06:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:14
DataPoint Verified.		23 Apr 2021 20:49:55
User closed query 'This is not on-going. Subject stopped the med on 07Dec2020' (Site from CRA).		23 Apr 2021 20:49:53
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
Query 'This is not on-going. Subject stopped the med on 07Dec2020' answered with 'updated . Thank you.' (Site from CRA).	(b) (4)	21 Apr 2021 21:24:27
Signature has been broken.	Oluwatosin Akingbala	21 Apr 2021 21:24:21
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	21 Apr 2021 21:24:21
User opened query 'This is not on-going. Subject stopped the med on 07Dec2020' (Site from CRA).	Oluwatosin Akingbala	21 Apr 2021 20:45:44
User signature succeeded.	(b) (4), (b) (6)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	William Seger (b) (4)	17 Sep 2020 17:06:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:14
DataPoint Verified.		23 Apr 2021 20:49:57
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
Signature has been broken.	(b) (4) Oluwatosin Akingbala	21 Apr 2021 21:24:21
User entered '07 Dec 2020' reason for change: Per Query Resolution	(b) (4) Oluwatosin Akingbala	21 Apr 2021 21:24:21
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:06:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:14
DataPoint Verified.		23 Apr 2021 20:49:58
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:06:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:14
User entered empty.	System	17 Sep 2020 17:06:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:14
User entered empty.	System	17 Sep 2020 17:06:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:14
User entered empty.	System	17 Sep 2020 17:06:18

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:16
DataPoint Verified.		21 Apr 2021 20:45:49
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE INACT SPLIT 4V, PRODUCTSYNONYM: FLUZONE QUADRIVALENT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Nov 2020 20:01:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:01:44
Data point term sent to Coder	System	10 Nov 2020 20:01:00
User entered 'fluzone quadrivalent'	(b) (4), (b) (6)	10 Nov 2020 20:00:12

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:16
DataPoint Verified.		21 Apr 2021 20:45:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:00:12

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:16
DataPoint Verified.		21 Apr 2021 20:45:54
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'influenza'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:00:12

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:16
DataPoint Verified.		21 Apr 2021 20:45:56
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0.7'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:00:12

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:16
DataPoint Verified.		21 Apr 2021 20:45:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:00:12

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:16
DataPoint Verified.		21 Apr 2021 20:45:59
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:00:12

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:16
DataPoint Verified.		21 Apr 2021 20:46:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:00:12

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:16
DataPoint Verified.		21 Apr 2021 20:46:02
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:00:12

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:16
DataPoint Verified.		21 Apr 2021 20:46:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:00:12

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:16
DataPoint Verified.		21 Apr 2021 20:46:05
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:00:12

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:16
DataPoint Verified.		21 Apr 2021 20:46:07
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '17 Oct 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:00:12

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:16
DataPoint Verified.		21 Apr 2021 20:46:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:00:12

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:16
DataPoint Verified.		21 Apr 2021 20:46:10
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:00:12

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:16
DataPoint Verified.		21 Apr 2021 20:46:11
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '17 Oct 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:00:12

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:16
DataPoint Verified.		21 Apr 2021 20:46:13
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:00:12

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:16
User entered empty.	System	10 Nov 2020 20:00:12

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:16
User entered empty.	System	10 Nov 2020 20:00:12

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:16
User entered empty.	System	10 Nov 2020 20:00:12

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:21
DataPoint Verified.		21 Apr 2021 20:46:16
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Feb 2021 14:58:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 14:58:47
Data point term sent to Coder	System	28 Jan 2021 13:34:50
User entered 'percocet'	Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:34:13

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:21
DataPoint Verified.		21 Apr 2021 20:46:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4)	
	Tisha Davis (b) (4)	28 Jan 2021 13:34:13
	(b) (4)	

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:21
DataPoint Verified.		21 Apr 2021 20:46:20
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'pain in right hip due to hip replacement surgery'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:34:13

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:21
DataPoint Verified.		21 Apr 2021 20:46:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '5/325'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:34:13

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:21
DataPoint Verified.		21 Apr 2021 20:46:27
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'mg (mg)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:34:13

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:21
DataPoint Verified.		21 Apr 2021 20:46:29
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:34:13

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:21
DataPoint Verified.		21 Apr 2021 20:46:30
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'as needed (PRN)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:34:13

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:21
DataPoint Verified.		21 Apr 2021 20:46:32
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:34:13

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:21
DataPoint Verified.		21 Apr 2021 20:46:34
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Oral (ORAL)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:34:13

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:21
DataPoint Verified.		21 Apr 2021 20:46:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:34:13

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:21
DataPoint Verified.		21 Apr 2021 20:46:37
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '07 Dec 2020'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:34:13

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:21
DataPoint Verified.		21 Apr 2021 20:46:39
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:34:13

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:21
DataPoint Verified.		21 Apr 2021 20:46:41
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
Signature has been broken.	(b) (4)	
	Oluwatosin Akingbala	24 Feb 2021 01:38:10
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Oluwatosin Akingbala	24 Feb 2021 01:38:10
	(b) (4)	
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
	(b) (4)	
User entered 'Yes (Y)'	Tisha Davis (b) (4)	28 Jan 2021 13:34:13
	(b) (4)	

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:21
DataPoint Verified.		21 Apr 2021 20:46:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
Signature has been broken.	(b) (4) Oluwatosin Akingbala	24 Feb 2021 01:38:10
User entered '06 Jan 2021' reason for change: New Information	(b) (4) Oluwatosin Akingbala	24 Feb 2021 01:38:10
User signature succeeded.	(b) (4) William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Tisha Davis (b) (4)	28 Jan 2021 13:34:13
	(b) (4)	

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:21
DataPoint Verified.		21 Apr 2021 20:46:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:34:13

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:21
User entered empty.	System	28 Jan 2021 13:34:13

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:21
User entered empty.	System	28 Jan 2021 13:34:13

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:21
User entered empty.	System	28 Jan 2021 13:34:13

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:25
DataPoint Verified.		21 Apr 2021 20:46:55
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Jan 2021 18:21:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 18:21:37
Data point term sent to Coder	System	28 Jan 2021 13:46:54
User entered 'lactated ringers solution'	Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:46:10

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:25
DataPoint Verified.		21 Apr 2021 20:46:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:46:10

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:25
DataPoint Verified.		21 Apr 2021 20:46:59
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
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	28 Jan 2021 13:46:38
User entered 'TV drip for surgery' reason for change: Tisha Davis	(b) (4)	28 Jan 2021 13:46:38
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 13:46:10
User entered empty.	Tisha Davis (b) (4)	28 Jan 2021 13:46:10
	(b) (4)	

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:25
DataPoint Verified.		21 Apr 2021 20:47:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '1,000'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:46:10

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:25
DataPoint Verified.		21 Apr 2021 20:47:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'mL (mL)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:46:10

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:25
DataPoint Verified.		21 Apr 2021 20:47:04
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:46:10

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:25
DataPoint Verified.		21 Apr 2021 20:47:06
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'other (OTHER)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:46:10

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:25
DataPoint Verified.		21 Apr 2021 20:47:12
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'continuous administration'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:46:10

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:25
DataPoint Verified.		21 Apr 2021 20:47:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:46:10

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:25
DataPoint Verified.		21 Apr 2021 20:47:16
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:46:10

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:25
DataPoint Verified.		21 Apr 2021 20:47:17
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '07 Dec 2020'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:46:10

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:25
DataPoint Verified.		21 Apr 2021 20:47:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:46:10

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:25
DataPoint Verified.		21 Apr 2021 20:47:20
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:46:10

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:25
DataPoint Verified.		21 Apr 2021 20:47:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '07 Dec 2020'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:46:10

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:25
DataPoint Verified.		21 Apr 2021 20:47:23
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:46:10

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:25
User entered empty.	System	28 Jan 2021 13:46:10

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:25
User entered empty.	System	28 Jan 2021 13:46:10

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:25
User entered empty.	System	28 Jan 2021 13:46:10

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:31
DataPoint Verified.		21 Apr 2021 20:47:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 10:47:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 10:47:01
Data point term sent to Coder	System	19 Apr 2021 19:50:25
Coding entries removed.	Alma Guel (b) (4)	19 Apr 2021 19:49:50
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:11:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 18:25:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 18:25:20
Data point term sent to Coder	System	28 Jan 2021 13:55:59
User entered 'Lidocaine PF'	Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:54:59

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:31
DataPoint Verified.		21 Apr 2021 20:47:29
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:54:59

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:31
DataPoint Verified.		21 Apr 2021 20:47:30
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'pain during hip surgery'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:54:59

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:31
DataPoint Verified.		21 Apr 2021 20:47:32
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0.3'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:54:59

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:31
DataPoint Verified.		21 Apr 2021 20:47:36
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'mL (mL)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:54:59

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:31
DataPoint Verified.		21 Apr 2021 20:47:37
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:54:59

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:31
DataPoint Verified.		21 Apr 2021 20:47:39
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'once (ONCE)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:54:59

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:31
DataPoint Verified.		21 Apr 2021 20:47:41
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:54:59

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:31
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:47:43
Signature has been broken.	Alma Guel (b) (4)	19 Apr 2021 19:49:50
User entered 'Other (OTHER)' reason for change:	Alma Guel (b) (4)	19 Apr 2021 19:49:50
Data Entry Error		
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:54:59

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:31
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:47:45
Signature has been broken.	Alma Guel (b) (4)	19 Apr 2021 19:49:50
User entered 'intradermal' reason for change: Data Entry Error	Alma Guel (b) (4)	19 Apr 2021 19:49:50
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:54:59

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:31
DataPoint Verified.		21 Apr 2021 20:47:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '07 Dec 2020'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:54:59

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:31
DataPoint Verified.		21 Apr 2021 20:47:48
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:54:59

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:31
DataPoint Verified.		21 Apr 2021 20:47:50
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4)	
	Tisha Davis (b) (4)	28 Jan 2021 13:54:59
	(b) (4)	

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:31
DataPoint Verified.		21 Apr 2021 20:47:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '07 Dec 2020'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:54:59

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:31
DataPoint Verified.		21 Apr 2021 20:47:53
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4)	
	Tisha Davis (b) (4)	28 Jan 2021 13:54:59
	(b) (4)	

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:31
User entered empty.	System	28 Jan 2021 13:54:59

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:31
User entered empty.	System	28 Jan 2021 13:54:59

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:31
User entered empty.	System	28 Jan 2021 13:54:59

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:36
DataPoint Verified.		21 Apr 2021 20:47:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Jan 2021 17:41:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 17:41:20
Data point term sent to Coder	System	28 Jan 2021 13:58:00
User entered 'Hydromorphone (Dilaudid)'	Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:57:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:36
DataPoint Verified.		21 Apr 2021 20:47:59
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:57:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:36
DataPoint Verified.		21 Apr 2021 20:48:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'pain during hip surgery'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:57:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:36
DataPoint Verified.		21 Apr 2021 20:48:05
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0.2'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:57:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:36
DataPoint Verified.		21 Apr 2021 20:48:07
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'mL (mL)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:57:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:36
DataPoint Verified.		21 Apr 2021 20:48:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:57:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:36
DataPoint Verified.		21 Apr 2021 20:48:11
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'as needed (PRN)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:57:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:36
DataPoint Verified.		21 Apr 2021 20:48:12
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:57:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:36
DataPoint Verified.		21 Apr 2021 20:48:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:57:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:36
DataPoint Verified.		21 Apr 2021 20:48:15
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:57:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:36
DataPoint Verified.		21 Apr 2021 20:48:17
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '07 Dec 2020'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:57:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:36
DataPoint Verified.		21 Apr 2021 20:48:18
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:57:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:36
DataPoint Verified.		21 Apr 2021 20:48:20
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4)	
	Tisha Davis (b) (4)	28 Jan 2021 13:57:39
	(b) (4)	

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:36
DataPoint Verified.		21 Apr 2021 20:48:21
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '07 Dec 2020'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:57:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:36
DataPoint Verified.		21 Apr 2021 20:48:23
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 13:57:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:36
User entered empty.	System	28 Jan 2021 13:57:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:36
User entered empty.	System	28 Jan 2021 13:57:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:11:36
User entered empty.	System	28 Jan 2021 13:57:39

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:50:23
User closed query 'Per medical records it should be ecotrin or Aspirin EC. Please change the response' (Site from CRA).		23 Apr 2021 20:50:20
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 05:11:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:11:55
Query 'Per medical records it should be ecotrin or Aspirin EC. Please change the response' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	21 Apr 2021 21:07:24
Data point term sent to Coder	System	21 Apr 2021 21:07:20
Coding entries removed.	Alma Guel (b) (4)	21 Apr 2021 21:06:28
Coding entries removed.	Alma Guel (b) (4)	21 Apr 2021 21:06:28
Signature has been broken.	Alma Guel (b) (4)	21 Apr 2021 21:06:28
User entered 'ASPIRIN ecotrin' reason for change:	Alma Guel (b) (4)	21 Apr 2021 21:06:28
Data Entry Error		
User opened query 'Per medical records it should be ecotrin or Aspirin EC. Please change the response' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:34:15
DataPoint Un-verified.		19 Apr 2021 18:35:41
DataPoint Verified.		19 Apr 2021 18:33:09
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:11:17

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 14:00:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 14:00:19
Data point term sent to Coder	System	28 Jan 2021 14:00:06
User entered 'Aspirin'	Tisha Davis (b) (4)	28 Jan 2021 14:00:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:11
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:00:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:50:25
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Alma Guel (b) (4)	21 Apr 2021 21:06:28
User entered 'DVT' reason for change: Data Entry	Alma Guel (b) (4)	21 Apr 2021 21:06:28
Error		
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:35:43
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'preventative'	(b) (4)	
	Tisha Davis (b) (4)	28 Jan 2021 14:00:03
	(b) (4)	

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:48:38
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '325'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:00:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:48:40
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'mg (mg)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:00:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:48:41
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:00:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:48:44
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'twice daily (BID)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:00:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:48:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:00:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:48:47
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Oral (ORAL)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:00:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:48:48
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:00:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:48:49
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '07 Dec 2020'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:00:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:48:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:00:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:51:21
User closed query 'This is on-going. Please change the response. ' (Site from CRA).		23 Apr 2021 20:51:19
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
Query 'This is on-going. Please change the response. ' answered with 'updated' (Site from CRA).	(b) (4)	
Signature has been broken.	Alma Guel (b) (4)	21 Apr 2021 21:07:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Alma Guel (b) (4)	21 Apr 2021 21:07:17
User opened query 'This is on-going. Please change the response. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 21:07:17
DataPoint Un-verified.		21 Apr 2021 20:49:31
DataPoint Verified.		21 Apr 2021 20:49:09
User signature succeeded.	William Seger (b) (4)	21 Apr 2021 20:48:53
User entered 'No (N)'	(b) (4)	13 Feb 2021 00:11:17
	Tisha Davis (b) (4)	28 Jan 2021 14:00:03
	(b) (4)	

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:51:23
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	21 Apr 2021 21:07:46
DataPoint Un-verified.	Alma Guel (b) (4)	21 Apr 2021 21:07:46
Signature has been broken.	Alma Guel (b) (4)	21 Apr 2021 21:07:46
User entered empty; reason for change Data Entry Error	Alma Guel (b) (4)	21 Apr 2021 21:07:46
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	21 Apr 2021 21:07:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:48:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '08 Dec 2020'	Tisha Davis (b) (4)	28 Jan 2021 14:00:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:48:59
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:00:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Jan 2021 14:00:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jan 2021 14:00:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Jan 2021 14:00:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:36
DataPoint Verified.		23 Apr 2021 20:51:53
User closed query 'No entry in source. Please take necessary actions as applicable' (Site from CRA).		23 Apr 2021 20:51:51
Query 'No entry in source. Please take necessary actions as applicable' answered with 'source updated . Thank you.' (Site from CRA).	Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:31:18
User opened query 'No entry in source. Please take necessary actions as applicable' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:51:04
DataPoint Un-verified.		21 Apr 2021 20:50:29
DataPoint Verified.		21 Apr 2021 20:49:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: IRRIGATING SOLUTIONS, ATC: SALT SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:09:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 16:09:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 10:08:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 10:08:36
Data point term sent to Coder	System	24 Mar 2021 16:19:10
Data point term sent to Coder	System	24 Mar 2021 00:47:03
Coding entries removed.	Oluwatosin Akingbala (b) (4)	24 Mar 2021 00:46:53

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:16:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:16:56
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:11:17
Data point term sent to Coder	System	28 Jan 2021 14:10:16
User entered 'sodium cholride (Ns Flush)'	Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:10:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:36
DataPoint Verified.		23 Apr 2021 20:51:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Yes (Y)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:10:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:36
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:51:58
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User closed query 'Per CDM re-query: Please update the indication term to match the AE term for reconciliation of data. ' (Site from DM).	(b) (4)	(b) (4), (b) (6)
Query 'Per CDM re-query: Please update the indication term to match the AE term for reconciliation of data. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 13:00:11
User entered 'right hip replacement' reason for change: Per Query Resolution	(b) (4), (b) (6)	24 Mar 2021 16:18:33
User closed query 'Per CDM re-query: Per previous query, please update the Indication to include details of the AE this medication relates to.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 16:18:27
User opened query 'Per CDM re-query: Please update the indication term to match the AE term for reconciliation of data. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 07:31:59
Query 'Per CDM re-query: Per previous query, please update the Indication to include details of the AE this medication relates to.' answered with 'updated.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 07:31:57
Signature has been broken.	Oluwatosin Akingbala (b) (4)	24 Mar 2021 00:47:04
User entered 'SALINE FLUSH for surgery' reason for change: Per Query Resolution	Oluwatosin Akingbala (b) (4)	24 Mar 2021 00:46:53
User opened query 'Per CDM re-query: Per previous query, please update the Indication to include details of the AE this medication relates to.' (Site from DM).	Oluwatosin Akingbala (b) (4)	24 Mar 2021 00:46:53
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 10:27:31
	(b) (4), (b) (6)	15 Mar 2021 10:27:31

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'this was used during the surgery for the AE' (Site from DM).	Tisha Davis (b) (4) (b) (4)	12 Mar 2021 19:22:07
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:40:04
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:11:17
User entered 'saline flush'	Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:10:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:36
DataPoint Verified.		23 Apr 2021 20:52:02
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '2'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:10:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:36
DataPoint Verified.		23 Apr 2021 20:52:06
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'mL (mL)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:10:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:36
DataPoint Verified.		23 Apr 2021 20:52:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:10:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:36
DataPoint Verified.		23 Apr 2021 20:52:09
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'twice daily (BID)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:10:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:36
DataPoint Verified.		23 Apr 2021 20:52:13
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:10:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:36
DataPoint Verified.		23 Apr 2021 20:52:14
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:10:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:36
DataPoint Verified.		23 Apr 2021 20:52:17
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered empty.	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:10:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:36
DataPoint Verified.		23 Apr 2021 20:52:21
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '07 Dec 2020'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:10:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:36
DataPoint Verified.		23 Apr 2021 20:52:23
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '0'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:10:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:36
DataPoint Verified.		23 Apr 2021 20:52:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:10:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:36
DataPoint Verified.		23 Apr 2021 20:52:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '08 Dec 2020'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:10:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:36
DataPoint Verified.		23 Apr 2021 20:52:28
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'No (N)'	(b) (4) Tisha Davis (b) (4) (b) (4)	28 Jan 2021 14:10:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:36
User entered '2'	System	28 Jan 2021 14:10:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:36
User entered '1'	System	28 Jan 2021 14:10:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:36
User entered '804 (804)'	System	28 Jan 2021 14:10:03

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:52:54
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL, PRODUCTS YNOMY: POLYETHYLENE GLYCOL [MACROGOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 06:05:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 06:05:59
Data point term sent to Coder	System	21 Apr 2021 21:38:03
User entered 'polyethylene glycol'	Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:37:40

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:52:59
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:37:40

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:53:04
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'stool softener'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:37:40

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:53:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '17'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:37:40

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:53:07
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'g (g)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:37:40

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:53:13
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:37:40

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:53:15
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'once daily (QD)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:37:40

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:53:17
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:37:40

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:53:18
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Oral (ORAL)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:37:40

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:53:26
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:37:40

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:53:28
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:37:40

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:53:30
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:37:40

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:53:32
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:37:40

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:53:34
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:37:40

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 20:53:36
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:37:40

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 21:37:40

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 21:37:40

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 21:37:40

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:52
DataPoint Verified.		23 Apr 2021 20:53:49
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: DIAZEPAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 05:18:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:18:53
Data point term sent to Coder	System	21 Apr 2021 21:40:05
User entered 'diazepam solution'	Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:39:28

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:52
DataPoint Verified.		23 Apr 2021 20:53:58
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:39:28

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:52
DataPoint Verified.		23 Apr 2021 20:54:00
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'iv drip for surgery'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:39:28

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:52
DataPoint Verified.		23 Apr 2021 20:54:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '5'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:39:28

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:52
DataPoint Verified.		23 Apr 2021 20:54:06
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'mg (mg)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:39:28

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:52
DataPoint Verified.		23 Apr 2021 20:54:08
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:39:28

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:52
DataPoint Verified.		23 Apr 2021 20:54:10
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'once (ONCE)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:39:28

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:52
DataPoint Verified.		23 Apr 2021 20:54:23
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:39:28

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:52
DataPoint Verified.		23 Apr 2021 20:54:30
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:39:28

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:52
DataPoint Verified.		23 Apr 2021 20:54:32
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:39:28

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:52
DataPoint Verified.		23 Apr 2021 20:54:34
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:39:28

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:52
DataPoint Verified.		23 Apr 2021 20:54:36
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:39:28

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:52
DataPoint Verified.		23 Apr 2021 20:54:38
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:39:28

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:52
DataPoint Verified.		23 Apr 2021 20:54:40
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:39:28

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:52
DataPoint Verified.		23 Apr 2021 20:54:41
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:39:28

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:52
User entered empty.	System	21 Apr 2021 21:39:28

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:52
User entered empty.	System	21 Apr 2021 21:39:28

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:52
User entered empty.	System	21 Apr 2021 21:39:28

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:59
DataPoint Verified.		23 Apr 2021 20:55:29
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 05:28:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:28:52
Data point term sent to Coder	System	21 Apr 2021 21:42:06
User entered 'fentanyl solution'	Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:41:25

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:59
DataPoint Verified.		23 Apr 2021 20:55:30
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:41:25

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:59
DataPoint Verified.		23 Apr 2021 20:55:52
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'iv drip for surgery'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:41:25

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:59
DataPoint Verified.		23 Apr 2021 20:56:02
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '100'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:41:25

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:59
DataPoint Verified.		23 Apr 2021 20:56:03
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'ug (ug)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:41:25

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:59
DataPoint Verified.		23 Apr 2021 20:56:23
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:41:25

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:59
DataPoint Verified.		23 Apr 2021 20:56:25
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'as needed (PRN)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:41:25

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:59
DataPoint Verified.		23 Apr 2021 20:56:26
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:41:25

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:59
DataPoint Verified.		23 Apr 2021 20:56:35
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:41:25

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:59
DataPoint Verified.		23 Apr 2021 20:56:36
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:41:25

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:59
DataPoint Verified.		23 Apr 2021 20:56:42
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:41:25

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:59
DataPoint Verified.		23 Apr 2021 20:56:44
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:41:25

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:59
DataPoint Verified.		23 Apr 2021 20:56:46
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:41:25

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:59
DataPoint Verified.		23 Apr 2021 20:56:47
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:41:25

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:59
DataPoint Verified.		23 Apr 2021 20:56:48
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:41:25

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:59
User entered empty.	System	21 Apr 2021 21:41:25

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:59
User entered empty.	System	21 Apr 2021 21:41:25

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:12:59
User entered empty.	System	21 Apr 2021 21:41:25

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:13
DataPoint Verified.		23 Apr 2021 20:58:25
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 05:57:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:57:55
Data point term sent to Coder	System	21 Apr 2021 21:43:07
User entered 'morphine solution'	Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:42:57

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:13
DataPoint Verified.		23 Apr 2021 20:58:26
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:42:57

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:13
DataPoint Verified.		23 Apr 2021 20:58:33
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'iv drip surgery'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:42:57

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:13
DataPoint Verified.		23 Apr 2021 20:58:37
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '5'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:42:57

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:13
DataPoint Verified.		23 Apr 2021 20:58:39
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'mg (mg)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:42:57

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:13
DataPoint Verified.		23 Apr 2021 20:58:40
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:42:57

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:13
DataPoint Verified.		23 Apr 2021 20:58:48
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'twice daily (BID)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:42:57

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:13
DataPoint Verified.		23 Apr 2021 20:58:50
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:42:57

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:13
DataPoint Verified.		23 Apr 2021 20:58:51
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:42:57

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:13
DataPoint Verified.		23 Apr 2021 20:58:53
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:42:57

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:13
DataPoint Verified.		23 Apr 2021 20:59:03
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:42:57

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:13
DataPoint Verified.		23 Apr 2021 20:59:04
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:42:57

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:13
DataPoint Verified.		23 Apr 2021 20:59:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:42:57

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:13
DataPoint Verified.		23 Apr 2021 20:59:07
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:42:57

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:13
DataPoint Verified.		23 Apr 2021 20:59:09
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:42:57

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:13
User entered '2'	System	21 Apr 2021 21:42:57

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:13
User entered '1'	System	21 Apr 2021 21:42:57

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:13
User entered '804 (804)'	System	21 Apr 2021 21:42:57

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:28
DataPoint Verified.		23 Apr 2021 20:59:17
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 05:58:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:58:58
Data point term sent to Coder	System	21 Apr 2021 21:45:08
User entered 'lidocaine PF solution'	Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:44:19

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:28
DataPoint Verified.		23 Apr 2021 21:01:18
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:44:19

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:28
DataPoint Verified.		23 Apr 2021 21:01:25
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'iv drip for surgery'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:44:19

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:28
DataPoint Verified.		23 Apr 2021 21:01:26
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '50'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:44:19

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:28
DataPoint Verified.		23 Apr 2021 21:01:28
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'mg (mg)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:44:19

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:28
DataPoint Verified.		23 Apr 2021 21:01:32
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:44:19

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:28
DataPoint Verified.		23 Apr 2021 21:01:41
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'as needed (PRN)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:44:19

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:28
DataPoint Verified.		23 Apr 2021 21:01:42
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:44:19

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:28
DataPoint Verified.		23 Apr 2021 21:01:44
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:44:19

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:28
DataPoint Verified.		23 Apr 2021 21:01:48
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:44:19

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:28
DataPoint Verified.		23 Apr 2021 21:01:54
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:44:19

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:28
DataPoint Verified.		23 Apr 2021 21:01:56
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:44:19

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:28
DataPoint Verified.		23 Apr 2021 21:01:57
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:44:19

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:28
DataPoint Verified.		23 Apr 2021 21:01:59
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:44:19

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:28
DataPoint Verified.		23 Apr 2021 21:02:00
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:44:19

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:28
User entered empty.	System	21 Apr 2021 21:44:19

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:28
User entered empty.	System	21 Apr 2021 21:44:19

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:13:28
User entered empty.	System	21 Apr 2021 21:44:19

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:53
DataPoint Verified.		23 Apr 2021 21:02:19
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 07:07:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 07:07:55
Data point term sent to Coder	System	21 Apr 2021 21:46:13
User entered 'propofol emulsion'	Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:45:47

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:53
DataPoint Verified.		23 Apr 2021 21:02:26
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:45:47

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:53
DataPoint Verified.		23 Apr 2021 21:02:30
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'iv drip for surgery'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:45:47

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:53
DataPoint Verified.		23 Apr 2021 21:02:32
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '10'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:45:47

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:53
DataPoint Verified.		23 Apr 2021 21:02:33
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'mg (mg)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:45:47

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:53
DataPoint Verified.		23 Apr 2021 21:02:39
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:45:47

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:53
DataPoint Verified.		23 Apr 2021 21:02:41
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'as needed (PRN)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:45:47

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:53
DataPoint Verified.		23 Apr 2021 21:02:47
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:45:47

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:53
DataPoint Verified.		23 Apr 2021 21:02:53
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:45:47

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:53
DataPoint Verified.		23 Apr 2021 21:02:55
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:45:47

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:53
DataPoint Verified.		23 Apr 2021 21:02:57
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:45:47

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:53
DataPoint Verified.		23 Apr 2021 21:02:59
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:45:47

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:53
DataPoint Verified.		23 Apr 2021 21:03:00
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:45:47

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:53
DataPoint Verified.		23 Apr 2021 21:03:02
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:45:47

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:53
DataPoint Verified.		23 Apr 2021 21:03:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:45:47

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:53
User entered empty.	System	21 Apr 2021 21:45:47

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:53
User entered empty.	System	21 Apr 2021 21:45:47

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:53
User entered empty.	System	21 Apr 2021 21:45:47

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:58
DataPoint Verified.		23 Apr 2021 21:06:35
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: ROCURONIUM - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 07:11:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 07:11:42
Data point term sent to Coder	System	21 Apr 2021 21:49:15
User entered 'rocuronium solution'	Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:48:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:58
DataPoint Verified.		23 Apr 2021 21:06:39
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:48:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:58
DataPoint Verified.		23 Apr 2021 21:06:41
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'iv drip for surgery'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:48:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:58
DataPoint Verified.		23 Apr 2021 21:06:44
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '30'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:48:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:58
DataPoint Verified.		23 Apr 2021 21:06:48
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'mg (mg)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:48:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:58
DataPoint Verified.		23 Apr 2021 21:06:49
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:48:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:58
DataPoint Verified.		23 Apr 2021 21:06:51
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'as needed (PRN)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:48:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:58
DataPoint Verified.		23 Apr 2021 21:06:53
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:48:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:58
DataPoint Verified.		23 Apr 2021 21:06:59
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:48:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:58
DataPoint Verified.		23 Apr 2021 21:07:01
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:48:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:58
DataPoint Verified.		23 Apr 2021 21:07:02
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:48:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:58
DataPoint Verified.		23 Apr 2021 21:07:07
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:48:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:58
DataPoint Verified.		23 Apr 2021 21:07:09
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:48:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:58
DataPoint Verified.		23 Apr 2021 21:07:12
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:48:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:58
DataPoint Verified.		23 Apr 2021 21:07:14
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:48:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:58
User entered empty.	System	21 Apr 2021 21:48:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:58
User entered empty.	System	21 Apr 2021 21:48:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:14:58
User entered empty.	System	21 Apr 2021 21:48:22

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:05
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: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 10:05:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 10:05:43
Data point term sent to Coder	System	23 Apr 2021 21:32:55
Coding entries removed.	Alma Guel (b) (4)	23 Apr 2021 21:32:00
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:07:23
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Apr 2021 17:39:39
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: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:22:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:22:46
Data point term sent to Coder	System	21 Apr 2021 21:50:17
User entered 'dexamethasone'	Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:49:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:05
DataPoint Verified.		23 Apr 2021 21:07:33
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:49:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:05
DataPoint Verified.		23 Apr 2021 21:07:38
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'iv drip for surgery'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:49:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:05
DataPoint Verified.		23 Apr 2021 21:07:43
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '8'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:49:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:05
DataPoint Verified.		23 Apr 2021 21:07:44
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'mg (mg)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:49:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:05
DataPoint Verified.		23 Apr 2021 21:07:46
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:49:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:05
DataPoint Verified.		23 Apr 2021 21:07:48
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'as needed (PRN)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:49:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:05
DataPoint Verified.		23 Apr 2021 21:07:55
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:49:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:05
User signature succeeded.	William Seger (b) (4)	28 Apr 2021 07:45:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:34:25
User closed query 'Per source route of administration is IV. Please change the response accordingly.' (Site from CRA).		23 Apr 2021 21:34:21
Query 'Per source route of administration is IV. Please change the response accordingly.' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	23 Apr 2021 21:32:20
Signature has been broken.	Alma Guel (b) (4)	23 Apr 2021 21:32:00
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Alma Guel (b) (4)	23 Apr 2021 21:32:00
User opened query 'Per source route of administration is IV. Please change the response accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 21:15:06
DataPoint Un-verified.		23 Apr 2021 21:14:39
DataPoint Verified.		23 Apr 2021 21:12:13
DataPoint Un-verified.		23 Apr 2021 21:12:12
DataPoint Verified.		23 Apr 2021 21:07:57
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:49:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:05
DataPoint Verified.		23 Apr 2021 21:09:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:49:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:05
DataPoint Verified.		23 Apr 2021 21:09:32
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:49:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:05
DataPoint Verified.		23 Apr 2021 21:09:33
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:49:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:05
DataPoint Verified.		23 Apr 2021 21:09:35
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:49:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:05
DataPoint Verified.		23 Apr 2021 21:09:37
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:49:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:05
DataPoint Verified.		23 Apr 2021 21:09:38
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:49:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:05
User entered empty.	System	21 Apr 2021 21:49:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:05
User entered empty.	System	21 Apr 2021 21:49:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:05
User entered empty.	System	21 Apr 2021 21:49:51

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:42:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
DataPoint Verified.		23 Apr 2021 21:12:22
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Apr 2021 05:28:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:28:20
Data point term sent to Coder	System	21 Apr 2021 21:52:18
User entered 'famotidine solution'	Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:52:08

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
DataPoint Verified.		23 Apr 2021 21:12:24
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
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	21 Apr 2021 21:52:25
User entered 'Yes (Y)' reason for change: Data Entry Error	System	21 Apr 2021 21:52:25
User opened query 'Data is required. Please complete.' (Site from System).	Oluwatosin Akingbala	21 Apr 2021 21:52:25
User entered empty.	(b) (4)	
	System	21 Apr 2021 21:52:08
	Oluwatosin Akingbala	21 Apr 2021 21:52:08
	(b) (4)	

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
DataPoint Verified.		23 Apr 2021 21:12:25
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'iv drip for surgery'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:52:08

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
DataPoint Verified.		23 Apr 2021 21:12:27
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '20'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:52:08

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
DataPoint Verified.		23 Apr 2021 21:12:29
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'mg (mg)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:52:08

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
DataPoint Verified.		23 Apr 2021 21:12:30
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:52:08

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
DataPoint Verified.		23 Apr 2021 21:12:32
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'as needed (PRN)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:52:08

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
DataPoint Verified.		23 Apr 2021 21:12:53
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:52:08

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
DataPoint Verified.		23 Apr 2021 21:14:31
Query 'Per source, the route of administration is IV' canceled (Site from CRA).		23 Apr 2021 21:14:28
User opened query 'Per source, the route of administration is IV' (Site from CRA).		23 Apr 2021 21:13:50
DataPoint Un-verified.		23 Apr 2021 21:13:32
DataPoint Verified.		23 Apr 2021 21:12:55
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4)	21 Apr 2021 21:52:08
	Oluwatosin Akingbala (b) (4)	

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
DataPoint Verified.		23 Apr 2021 21:12:57
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:52:08

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
DataPoint Verified.		23 Apr 2021 21:13:01
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:52:08

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
DataPoint Verified.		23 Apr 2021 21:13:03
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:52:08

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
DataPoint Verified.		23 Apr 2021 21:13:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:52:08

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
DataPoint Verified.		23 Apr 2021 21:13:06
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:52:08

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
DataPoint Verified.		23 Apr 2021 21:13:08
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:52:08

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
User entered empty.	System	21 Apr 2021 21:52:08

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
User entered empty.	System	21 Apr 2021 21:52:08

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
User entered empty.	System	21 Apr 2021 21:52:08

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:42:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
DataPoint Verified.		23 Apr 2021 21:13:19
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: ANTIFIBRINOLYTICS, ATC: AMINO ACIDS, PRODUCT: TRANEXAMIC ACID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 06:11:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:11:51
Data point term sent to Coder	System	21 Apr 2021 21:58:27
User entered 'TRANEXAMIC ACID solution' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 21:57:46
Data point term sent to Coder	System	21 Apr 2021 21:55:22
User entered 'tranexamic acid'	Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:54:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
DataPoint Verified.		23 Apr 2021 21:13:20
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:54:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
DataPoint Verified.		23 Apr 2021 21:13:22
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'iv drip for surgery'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:54:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
DataPoint Verified.		23 Apr 2021 21:13:24
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '1000'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:54:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
DataPoint Verified.		23 Apr 2021 21:13:25
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'mg (mg)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:54:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
DataPoint Verified.		23 Apr 2021 21:13:27
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:54:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
DataPoint Verified.		23 Apr 2021 21:14:22
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'as needed (PRN)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:54:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
DataPoint Verified.		23 Apr 2021 21:15:33
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:54:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
DataPoint Verified.		23 Apr 2021 21:15:39
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:54:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
DataPoint Verified.		23 Apr 2021 21:15:41
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:54:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
DataPoint Verified.		23 Apr 2021 21:15:48
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:54:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
DataPoint Verified.		23 Apr 2021 21:15:50
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:54:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
DataPoint Verified.		23 Apr 2021 21:15:51
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:54:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
DataPoint Verified.		23 Apr 2021 21:15:54
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:54:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
DataPoint Verified.		23 Apr 2021 21:15:55
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:54:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
User entered empty.	System	21 Apr 2021 21:54:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
User entered empty.	System	21 Apr 2021 21:54:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
User entered empty.	System	21 Apr 2021 21:54:26

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:11
DataPoint Verified.		23 Apr 2021 21:16:14
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: PARASYMPATHOMIMETICS, ATC: ANTICHOLINESTERASES, PRODUCT: NEOSTIGMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 06:00:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:00:01
Data point term sent to Coder	System	21 Apr 2021 21:57:26
User entered 'neostigmine solution'	Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:56:49

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:11
DataPoint Verified.		23 Apr 2021 21:16:15
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:56:49

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:11
DataPoint Verified.		23 Apr 2021 21:16:31
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'iv drip for surgery'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:56:49

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:11
DataPoint Verified.		23 Apr 2021 21:16:37
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '3'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:56:49

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:11
DataPoint Verified.		23 Apr 2021 21:16:39
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'mg (mg)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:56:49

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:11
DataPoint Verified.		23 Apr 2021 21:16:58
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:56:49

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:11
DataPoint Verified.		23 Apr 2021 21:17:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'as needed (PRN)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:56:49

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:11
DataPoint Verified.		23 Apr 2021 21:17:07
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:56:49

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:11
DataPoint Verified.		23 Apr 2021 21:17:13
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:56:49

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:11
DataPoint Verified.		23 Apr 2021 21:17:23
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:56:49

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:11
DataPoint Verified.		23 Apr 2021 21:17:25
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:56:49

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:11
DataPoint Verified.		23 Apr 2021 21:17:27
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:56:49

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:11
DataPoint Verified.		23 Apr 2021 21:17:29
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:56:49

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:11
DataPoint Verified.		23 Apr 2021 21:19:22
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:56:49

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:11
DataPoint Verified.		23 Apr 2021 21:19:23
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:56:49

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:11
User entered empty.	System	21 Apr 2021 21:56:49

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:11
User entered empty.	System	21 Apr 2021 21:56:49

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:11
User entered empty.	System	21 Apr 2021 21:56:49

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:42:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:15
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: GLYCOPYRRONIUM BROMIDE, PRODUCTSYNONYM: GLYCOPYRROLATE [GLYCOPYRRONIUM BROMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 11:52:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 11:52:54
Data point term sent to Coder	System	23 Apr 2021 21:34:56
Coding entries removed.	Alma Guel (b) (4)	23 Apr 2021 21:34:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:20:48
User signature succeeded.	William Seger (b) (4) (b) (4)	23 Apr 2021 17:39:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: GLYCOPYRRONIUM, PRODUCTSYNONYM: GLYCOPYRROLATE [GLYCOPYRRONIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:41:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:41:47
Data point term sent to Coder	System	21 Apr 2021 22:00:28
User entered 'glycopyrrolate solution'	Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:59:46

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:15
DataPoint Verified.		23 Apr 2021 21:20:50
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:59:46

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:15
DataPoint Verified.		23 Apr 2021 21:20:59
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'iv drip for surgery'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:59:46

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:15
DataPoint Verified.		23 Apr 2021 21:21:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '0.6'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:59:46

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:15
DataPoint Verified.		23 Apr 2021 21:21:06
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'mg (mg)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:59:46

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:15
DataPoint Verified.		23 Apr 2021 21:21:08
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:59:46

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:15
DataPoint Verified.		23 Apr 2021 21:21:11
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'as needed (PRN)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:59:46

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:15
DataPoint Verified.		23 Apr 2021 21:21:24
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:59:46

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:15
User signature succeeded.	William Seger (b) (4)	28 Apr 2021 07:45:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 21:35:05
User closed query 'Per source its IV Bolus. Please change the response' (Site from CRA).		23 Apr 2021 21:35:02
Query 'Per source its IV Bolus. Please change the response' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	23 Apr 2021 21:34:57
Signature has been broken.	Alma Guel (b) (4)	23 Apr 2021 21:34:39
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)' reason for change: Data Entry Error	Alma Guel (b) (4)	23 Apr 2021 21:34:39
User opened query 'Per source its IV Bolus. Please change the response' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 21:24:47
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:59:46

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:15
DataPoint Verified.		23 Apr 2021 21:24:54
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:59:46

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:15
DataPoint Verified.		23 Apr 2021 21:24:56
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:59:46

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:15
DataPoint Verified.		23 Apr 2021 21:24:58
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:59:46

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:15
DataPoint Verified.		23 Apr 2021 21:25:02
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:59:46

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:15
DataPoint Verified.		23 Apr 2021 21:25:10
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:59:46

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:15
DataPoint Verified.		23 Apr 2021 21:25:12
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 21:59:46

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:15
User entered empty.	System	21 Apr 2021 21:59:46

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:15
User entered empty.	System	21 Apr 2021 21:59:46

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:15
User entered empty.	System	21 Apr 2021 21:59:46

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:42:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:26
DataPoint Verified.		23 Apr 2021 21:25:27
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 06:01:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:01:51
Data point term sent to Coder	System	21 Apr 2021 22:02:30
User entered 'ondansetron solution'	Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:01:41

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:26
DataPoint Verified.		23 Apr 2021 21:25:28
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:01:41

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:26
DataPoint Verified.		23 Apr 2021 21:25:33
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
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	21 Apr 2021 22:02:29
User entered 'iv drip for surgery' reason for change: Data Entry Error	System	21 Apr 2021 22:02:29
User opened query 'Data is required. Please complete.' (Site from System).	Oluwatosin Akingbala	21 Apr 2021 22:02:29
User entered empty.	(b) (4)	
	System	21 Apr 2021 22:01:41
	Oluwatosin Akingbala	21 Apr 2021 22:01:41
	(b) (4)	

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:26
DataPoint Verified.		23 Apr 2021 21:25:48
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '4'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:01:41

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:26
DataPoint Verified.		23 Apr 2021 21:25:49
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'mg (mg)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:01:41

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:26
DataPoint Verified.		23 Apr 2021 21:25:58
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:01:41

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:26
DataPoint Verified.		23 Apr 2021 21:25:59
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'as needed (PRN)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:01:41

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:26
DataPoint Verified.		23 Apr 2021 21:26:01
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:01:41

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:26
DataPoint Verified.		23 Apr 2021 21:26:15
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:01:41

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:26
DataPoint Verified.		23 Apr 2021 21:26:18
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:01:41

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:26
DataPoint Verified.		23 Apr 2021 21:26:20
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:01:41

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:26
DataPoint Verified.		23 Apr 2021 21:26:32
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:01:41

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:26
DataPoint Verified.		23 Apr 2021 21:26:34
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:01:41

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:26
DataPoint Verified.		23 Apr 2021 21:26:36
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:01:41

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:26
DataPoint Verified.		23 Apr 2021 21:26:39
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
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	21 Apr 2021 22:02:29
User entered 'No (N)' reason for change: Data Entry Error	System	21 Apr 2021 22:02:29
User entered 'No (N)' reason for change: Data Entry Error	Oluwatosin Akingbala	21 Apr 2021 22:02:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 22:01:41
User entered empty.	System	21 Apr 2021 22:01:41
User entered empty.	Oluwatosin Akingbala	21 Apr 2021 22:01:41
User entered empty.	(b) (4)	

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:26
User entered empty.	System	21 Apr 2021 22:01:41

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:26
User entered empty.	System	21 Apr 2021 22:01:41

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:26
User entered empty.	System	21 Apr 2021 22:01:41

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:26:49
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DETEMIR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 05:44:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:44:51
Data point term sent to Coder	System	21 Apr 2021 22:06:34
User entered 'insulin detemir'	Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:06:33

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:26:53
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:06:33

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:26:55
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Type 2 diabetes (DM II)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:06:33

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:26:57
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '27'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:06:33

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:26:59
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'IU (IU)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:06:33

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:27:01
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:06:33

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:27:10
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'twice daily (BID)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:06:33

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:42:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:27:11
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:06:33

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:27:13
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:06:33

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:27:14
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:06:33

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:27:19
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:06:33

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:27:21
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:06:33

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:27:23
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:06:33

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:27:25
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:06:33

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:27:27
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:06:33

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 22:06:33

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 22:06:33

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 22:06:33

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:27:36
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Apr 2021 22:10:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 22:10:40
Data point term sent to Coder	System	21 Apr 2021 22:09:36
User entered 'simvastatin'	Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:08:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:27:40
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:08:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:27:44
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'hypercholesterolemia'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:08:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:27:46
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '40'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:08:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:27:47
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'mg (mg)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:08:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:27:53
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:08:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:27:55
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'once daily (QD)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:08:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:27:59
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:08:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:28:01
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Oral (ORAL)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:08:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:28:03
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:08:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:28:05
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '07 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:08:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:28:09
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered '0'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:08:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:28:11
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:08:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:28:13
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:08:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:28:15
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:39
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Apr 2021 22:08:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 22:08:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 22:08:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 22:08:52

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:42:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:17:13
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Apr 2021 19:41:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	28 Apr 2021 19:41:47
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:28:26
Data point term sent to Coder	System	28 Apr 2021 19:09:23
User entered 'Lactaded Ringers Solution'	Alma Guel (b) (4)	28 Apr 2021 19:09:06

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:42:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:17:13
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:28:27
User entered 'Yes (Y)'	Alma Guel (b) (4)	28 Apr 2021 19:09:06

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:17:13
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:28:29
User entered 'IV Drip for Surgery'	Alma Guel (b) (4)	28 Apr 2021 19:09:06

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:42:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:17:13
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:28:32
User entered '100'	Alma Guel (b) (4)	28 Apr 2021 19:09:06

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:42:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:17:13
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:28:34
User entered 'mL (mL)'	Alma Guel (b) (4)	28 Apr 2021 19:09:06

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:42:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:17:13
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:28:36
User entered empty.	Alma Guel (b) (4)	28 Apr 2021 19:09:06

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:42:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:17:13
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:31:18
DataPoint Un-verified.	Alma Guel (b) (4)	28 Apr 2021 19:30:43
User entered 'other (OTHER)' reason for change:	Alma Guel (b) (4)	28 Apr 2021 19:30:43
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:28:39
User entered 'once (ONCE)'	Alma Guel (b) (4)	28 Apr 2021 19:09:06

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:42:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:17:13
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:31:19
DataPoint Un-verified.	Alma Guel (b) (4)	28 Apr 2021 19:30:43
User entered 'continuous' reason for change: Data Entry Error	Alma Guel (b) (4)	28 Apr 2021 19:30:43
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 19:28:43
User entered empty.	Alma Guel (b) (4)	28 Apr 2021 19:09:06

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:42:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:17:13
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:28:45
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Alma Guel (b) (4)	28 Apr 2021 19:09:06

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:42:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:17:13
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:31:22
User entered empty.	Alma Guel (b) (4)	28 Apr 2021 19:09:06

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:42:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:17:13
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:31:24
User entered '07 Dec 2020'	Alma Guel (b) (4)	28 Apr 2021 19:09:06

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:42:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:17:13
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:31:26
User entered '0'	Alma Guel (b) (4)	28 Apr 2021 19:09:06

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:42:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:17:13
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:31:28
User entered 'No (N)'	Alma Guel (b) (4)	28 Apr 2021 19:09:06

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:42:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:17:13
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered '07 Dec 2020'	Alma Guel (b) (4)	28 Apr 2021 19:09:06

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:42:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:17:13
User signature succeeded.	William Seger (b) (4)	29 Apr 2021 23:22:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 19:31:31
User entered 'No (N)'	Alma Guel (b) (4)	28 Apr 2021 19:09:06

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:42:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:17:13
User entered empty.	System	28 Apr 2021 19:09:06

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:17:13
User entered empty.	System	28 Apr 2021 19:09:06

US3442024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:42:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:17:13
User entered empty.	System	28 Apr 2021 19:09:06

US3442024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:42:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:20:40
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:29:37
User closed query 'Please enter R Hip Replacement' (Site from CRA).		25 Jan 2021 21:29:35
Query 'Please enter R Hip Replacement' answered with 'done' (Site from CRA).		25 Jan 2021 15:03:12
User entered 'Yes (Y)' reason for change: Data Entry Error		25 Jan 2021 15:02:43
User opened query 'Please enter R Hip Replacement' (Site from CRA).		22 Jan 2021 15:18:23
User entered 'No (N)'		02 Sep 2020 21:06:26

US3442024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:42:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:29:43
User entered '7 Dec 2020'		25 Jan 2021 15:05:12

US3442024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:42:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	14 Apr 2021 20:45:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:29:01
User closed query 'Per medical records it's "Total hip arthroplasty on the right. please change the response and also update it in source' (Site from CRA).		14 Apr 2021 16:29:00
Query 'Per medical records it's "Total hip arthroplasty on the right. please change the response and also update it in source' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	05 Apr 2021 20:11:34
Signature has been broken.	Alma Guel (b) (4)	05 Apr 2021 20:09:28
User entered 'Total hip arthroplasty on the right' reason for change: Data Entry Error	Alma Guel (b) (4)	05 Apr 2021 20:09:28
User opened query 'Per medical records it's "Total hip arthroplasty on the right. please change the response and also update it in source' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 19:32:38
DataPoint Un-verified.		05 Apr 2021 19:31:34
DataPoint Verified.		05 Apr 2021 19:24:29
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
DataPoint Un-verified.	(b) (4) Tisha Davis (b) (4)	04 Feb 2021 17:29:38
User entered 'Right Total hip arthroplasty' reason for change: Data Entry Error	(b) (4) Tisha Davis (b) (4)	04 Feb 2021 17:29:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:29:44
User entered 'right hip replacement'		25 Jan 2021 15:05:12

US3442024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Medical History is not an indication for this surgery. Please update the field with the appropriate indication. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:24:41
		05 Apr 2021 19:24:31
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).		24 Mar 2021 07:29:00
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'updated.' (Site from DM).	Oluwatosin Akingbala (b) (4)	24 Mar 2021 00:18:41
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:39:46
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User closed query 'Per DM CLR: Indication = OTHER, however, there is a corresponding AE condition recorded in AE eCRF page that matches this procedure. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 07:53:58
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	06 Mar 2021 16:12:52

US3442024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:42:11

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Indication = OTHER, however, there is a corresponding AE condition recorded in AE eCRF page that matches this procedure. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM).	Tisha Davis (b) (4)	06 Mar 2021 16:12:40
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	06 Mar 2021 16:12:28
Signature has been broken.	Tisha Davis (b) (4)	06 Mar 2021 16:12:28
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Tisha Davis (b) (4)	06 Mar 2021 16:12:28
User opened query 'Per DM CLR: Indication = OTHER, however, there is a corresponding AE condition recorded in AE eCRF page that matches this procedure. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 07:41:02
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Query 'Medical History is not an indication for this surgery. Please update the field with the appropriate indication. ' answered with 'data updated' (Site from CRA).	Tisha Davis (b) (4)	04 Feb 2021 17:18:37
User entered 'Other (OTHER)' reason for change: Data Entry Error	Tisha Davis (b) (4)	04 Feb 2021 17:18:23
User opened query 'Medical History is not an indication for this surgery. Please update the field with the appropriate indication. ' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 21:32:16
DataPoint Un-verified.		25 Jan 2021 21:29:48
DataPoint Verified.		25 Jan 2021 21:29:46
User entered 'Medical History (MH)'		25 Jan 2021 15:05:12

US3442024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:42:11

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 19:24:49
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
Signature has been broken.	(b) (4)	
	Tisha Davis (b) (4)	06 Mar 2021 16:12:52
	(b) (4)	
User entered empty; reason for change Data Entry Error	Tisha Davis (b) (4)	06 Mar 2021 16:12:52
	(b) (4)	
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
	(b) (4)	
User entered 'surgery' reason for change: Data Entry Error	Tisha Davis (b) (4)	04 Feb 2021 17:18:23
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 21:32:19
DataPoint Verified.		25 Jan 2021 21:32:17
User entered empty.		25 Jan 2021 15:05:12

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'USA-US017-2020-MRNA-1273-P301000007'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Yes (Y)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Yes (Y)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'William'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Seger'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User closed query 'Please change the street address to 4504' (Site from CRA).		14 Apr 2021 16:29:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
Query 'Please change the street address to 4504' answered with 'data updated' (Site from CRA).	(b) (4)	
Un-reviewed for Safety.	Alma Guel (b) (4)	12 Apr 2021 16:55:01
Signature has been broken.	Alma Guel (b) (4)	12 Apr 2021 16:54:44
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	12 Apr 2021 16:54:44
User opened query 'Please change the street address to 4504' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:17:10
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered '4505 Boat Club Road, Suite 400A'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Fort Worth'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) Alma Guel (b) (4)	12 Apr 2021 16:54:44

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered '76135'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:57:12
User entered 'US'	System	15 Dec 2020 14:44:35

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 17:44:58
User entered '4'	System	01 Mar 2021 19:46:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
	(b) (4)	
User entered '3'	System	29 Jan 2021 16:19:24
User entered '2'	System	29 Jan 2021 14:57:27
User entered '1'	System	15 Dec 2020 14:44:35

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'USA-US017-2020-MRNA-1273-P301000007'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Yes (Y)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Yes (Y)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'William'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Seger'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User closed query 'Please change the street address to 4504' (Site from CRA).		14 Apr 2021 16:29:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
Query 'Please change the street address to 4504' answered with 'data updated' (Site from CRA).	(b) (4)	
Un-reviewed for Safety.	Alma Guel (b) (4)	12 Apr 2021 16:55:01
Signature has been broken.	Alma Guel (b) (4)	12 Apr 2021 16:54:44
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	12 Apr 2021 16:54:44
User opened query 'Please change the street address to 4504' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:17:10
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered '4505 Boat Club Road, Suite 400A'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Fort Worth'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) Alma Guel (b) (4)	12 Apr 2021 16:54:44

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered '76135'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:57:12
User entered 'US'	System	15 Dec 2020 14:44:35

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 17:44:58
User entered '4'	System	01 Mar 2021 19:46:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
	(b) (4)	
User entered '3'	System	29 Jan 2021 16:19:24
User entered '2'	System	29 Jan 2021 14:57:27
User entered '1'	System	15 Dec 2020 14:44:35

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:42:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '15/Dec/2020 09:44'	(b) (4) System	15 Dec 2020 14:44:35

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:42:11

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)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:57:12
User entered 'I'		15 Dec 2020 14:44:35

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'USA-US017-2020-MRNA-1273-P301000007'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Yes (Y)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Yes (Y)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'William'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Seger'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User closed query 'Please change the street address to 4504' (Site from CRA).		14 Apr 2021 16:29:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
Query 'Please change the street address to 4504' answered with 'data updated' (Site from CRA).	(b) (4)	
Un-reviewed for Safety.	Alma Guel (b) (4)	12 Apr 2021 16:55:01
Signature has been broken.	Alma Guel (b) (4)	12 Apr 2021 16:54:44
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	12 Apr 2021 16:54:44
User opened query 'Please change the street address to 4504' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:17:10
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered '4505 Boat Club Road, Suite 400A'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Fort Worth'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) Alma Guel (b) (4)	12 Apr 2021 16:54:44

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered '76135'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:57:12
User entered 'US'	System	15 Dec 2020 14:44:35

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 17:44:58
User entered '4'	System	01 Mar 2021 19:46:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
	(b) (4)	
User entered '3'	System	29 Jan 2021 16:19:24
User entered '2'	System	29 Jan 2021 14:57:27
User entered '1'	System	15 Dec 2020 14:44:35

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:42:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '29/Jan/2021 14:57'	(b) (4) System	29 Jan 2021 14:57:27

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:42:11

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)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:19:08
User entered '1'		29 Jan 2021 14:57:27

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'USA-US017-2020-MRNA-1273-P301000007'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Yes (Y)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Yes (Y)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'William'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Seger'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User closed query 'Please change the street address to 4504' (Site from CRA).		14 Apr 2021 16:29:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
Query 'Please change the street address to 4504' answered with 'data updated' (Site from CRA).	(b) (4)	
Un-reviewed for Safety.	Alma Guel (b) (4)	12 Apr 2021 16:55:01
Signature has been broken.	Alma Guel (b) (4)	12 Apr 2021 16:54:44
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	12 Apr 2021 16:54:44
User opened query 'Please change the street address to 4504' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:17:10
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered '4505 Boat Club Road, Suite 400A'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Fort Worth'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) Alma Guel (b) (4)	12 Apr 2021 16:54:44

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered '76135'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:57:12
User entered 'US'	System	15 Dec 2020 14:44:35

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 17:44:58
User entered '4'	System	01 Mar 2021 19:46:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
	(b) (4)	
User entered '3'	System	29 Jan 2021 16:19:24
User entered '2'	System	29 Jan 2021 14:57:27
User entered '1'	System	15 Dec 2020 14:44:35

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:42:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered '29/Jan/2021 16:19'	(b) (4) System	29 Jan 2021 16:19:24

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:42:11

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)	14 Apr 2021 16:29:52
Reviewed for Safety.		01 Mar 2021 19:46:33
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:19:24

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'USA-US017-2020-MRNA-1273-P301000007'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Yes (Y)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Yes (Y)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'William'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Seger'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User closed query 'Please change the street address to 4504' (Site from CRA).		14 Apr 2021 16:29:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
Query 'Please change the street address to 4504' answered with 'data updated' (Site from CRA).	(b) (4)	
Un-reviewed for Safety.	Alma Guel (b) (4)	12 Apr 2021 16:55:01
Signature has been broken.	Alma Guel (b) (4)	12 Apr 2021 16:54:44
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	12 Apr 2021 16:54:44
User opened query 'Please change the street address to 4504' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:17:10
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered '4505 Boat Club Road, Suite 400A'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Fort Worth'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) Alma Guel (b) (4)	12 Apr 2021 16:54:44

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered '76135'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:57:12
User entered 'US'	System	15 Dec 2020 14:44:35

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 17:44:58
User entered '4'	System	01 Mar 2021 19:46:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
	(b) (4)	
User entered '3'	System	29 Jan 2021 16:19:24
User entered '2'	System	29 Jan 2021 14:57:27
User entered '1'	System	15 Dec 2020 14:44:35

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:42:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
User entered '01/Mar/2021 14:46'	(b) (4) System	01 Mar 2021 19:46:19

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:42:11

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)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:46:33
User entered 'I'		01 Mar 2021 19:46:19

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'USA-US017-2020-MRNA-1273-P301000007'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Yes (Y)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Yes (Y)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'No (N)'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'William'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Seger'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User closed query 'Please change the street address to 4504' (Site from CRA).		14 Apr 2021 16:29:48
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
Query 'Please change the street address to 4504' answered with 'data updated' (Site from CRA).	(b) (4)	
Un-reviewed for Safety.	Alma Guel (b) (4)	12 Apr 2021 16:55:01
Signature has been broken.	Alma Guel (b) (4)	12 Apr 2021 16:54:44
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	12 Apr 2021 16:54:44
User opened query 'Please change the street address to 4504' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 00:17:10
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered '4505 Boat Club Road, Suite 400A'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered 'Fort Worth'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered empty.	(b) (4) Alma Guel (b) (4)	12 Apr 2021 16:54:44

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:44:23
User entered '76135'	System	15 Dec 2020 14:43:37

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 14:57:12
User entered 'US'	System	15 Dec 2020 14:44:35

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:42:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 17:44:58
User entered '4'	System	01 Mar 2021 19:46:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:11:17
	(b) (4)	
User entered '3'	System	29 Jan 2021 16:19:24
User entered '2'	System	29 Jan 2021 14:57:27
User entered '1'	System	15 Dec 2020 14:44:35

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:42:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered '24/Mar/2021 13:44'	(b) (4) System	24 Mar 2021 17:44:58

US3442024

Folder: SAE USA-US017-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:42:11

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)	14 Apr 2021 16:29:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:16:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:44:58