

US3712064 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:24:11

All time stamps listed in this document are displayed in GMT

US3712064

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 00:15:04

Generated On: 10 Jun 2021 09:24:11

[Participant ID](#)

US3712064

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

US3712064

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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	SCRN

US3712064

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Date of Birth (MMM yyyy)	(b) (6) 1946
Age	74
Age Units	YEARS
Age (Derived)	74
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Date of Informed Consent (<i>dd MMM yyyy</i>)	10 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Condition	ALLERGY TO LOVENOX
Start date (dd MMM yyyy)	UN JUN 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)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Condition	HYPEROPIA
Start date (dd MMM yyyy)	UN UNK 1949
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 1949
Start Year (derived)	1949
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Condition	SENILE PURPURA
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)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Condition	OBSTRUCTIVE SLEEP APNEA
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)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Condition	COLON POLYPS (BENIGN)
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)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Condition	LEFT INGUINAL HERNIA
Start date (dd MMM yyyy)	13 MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	13 MAY 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAY 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Condition	LEFT INGUINAL HERNIA REPAIR
Start date (dd MMM yyyy)	13 MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	13 MAY 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAY 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Condition	BLADDER CANCER
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Condition	TOTAL HIP ARTHROPLASTY
Start date (dd MMM yyyy)	UN JUN 2019
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 JUN 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Condition	SCIATICA
Start date (dd MMM yyyy)	UN DEC 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)	DEC 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Condition	ADULT ATTENTION DEFICIT DISORDER
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)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Condition	RADICAL PROSTATECTOMY
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Condition	CYSTOSCOPY OF THE BLADDER
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Condition	OSTEOARTHRITIS IN RIGHT HIP
Start date (dd MMM yyyy)	UN JUN 2019
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 JUN 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUN 2019
Stop Year (derived)	2019

US3712064

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	09:39 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 09:39
Height (xxx.x)	182.8 cm
Weight (xxx.x)	94.8 kg
BMI (xxx.x)	28.36978 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

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

WORSHIP, RESTAURANTS,
GROCERY SHOPPING

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 23:39:09

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

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

What was the participant's randomization number? 191109

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

Height	182.5 cm
Weight	94.6 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

Height	182.5 cm
Weight	94.6 kg
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 SEP 2020
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 10:45
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

Height	182.5 cm
Weight	94.6 kg
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)	18 SEP 2020
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 13:10
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

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 SEP 2020

What was the treatment time? (00:00-23:59) 12:40 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 12:40

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 SEP 2020
Collection time (00:00-23:59)	10:49 (24 HR)
Collection date and time (derived)	18 SEP 2020 10:49

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 17:10:35

Generated On: 10 Jun 2021 09:24:11

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:54	18 SEP 2020 10:54
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

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

98.4 °F

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

Yes ☐
No ☒

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

PC Time Stamp 18 SEP 2020 13:08

PC Open Date & Time 18 SEP 2020 13:00

PC Close Date & Time 18 SEP 2020 15:30

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

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	18 SEP 2020 20:19
PC Open Date & Time	18 SEP 2020 16:25
PC Close Date & Time	19 SEP 2020 11:59

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:11

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

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 20:42

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:11

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 21:04

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:11

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

98.7 °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

21 SEP 2020 20:33

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:11

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 18:59

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:11

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 20:39

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:11

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 14:15

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 13:09

PC Open Date & Time

18 SEP 2020 13:00

PC Close Date & Time

18 SEP 2020 15:30

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

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 SEP 2020 20:19

PC Open Date & Time

18 SEP 2020 16:25

PC Close Date & Time

19 SEP 2020 11:59

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

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 SEP 2020 20:42

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

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 SEP 2020 21:04

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

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 SEP 2020 20:33

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:11

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 SEP 2020 18:59

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:11

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 SEP 2020 20:39

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:11

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 SEP 2020 14:15

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 13:11
PC Open Date & Time	18 SEP 2020 13:00
PC Close Date & Time	18 SEP 2020 15:30

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 20:20
PC Open Date & Time	18 SEP 2020 16:25
PC Close Date & Time	19 SEP 2020 11:59

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

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

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

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 ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 21:05
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 20:33
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

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 ☒

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EAB) (1725)

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

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

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

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 ☒

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EAB) (1725)

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US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 20:40
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 14:15
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3712064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712064

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712064

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3712064

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

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

Visit date (dd MMM yyyy)	16 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

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)	16 OCT 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 10:10
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

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)	16 OCT 2020
Time of assessment (00:00-23:59)	12:03 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 12:03
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3712064

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

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.

US3712064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

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) 16 OCT 2020

What was the treatment time? (00:00-23:59) 11:28 (24 HR)

Treatment Date and Time (derived) 16 OCT 2020 11:28

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

What was the frequency of the study treatment dosing? ONCE

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

US3712064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

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)	10:34 (24 HR)
Collection date and time (derived)	16 OCT 2020 10:34

US3712064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 17:10:35

Generated On: 10 Jun 2021 09:24:11

Collection date (dd MMM yyyy)			16 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:37	16 OCT 2020 10:37
Nasopharyngeal Swab 2	No		

US3712064

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

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

98.9 °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

16 OCT 2020 12:11

PC Open Date & Time

16 OCT 2020 11:48

PC Close Date & Time

16 OCT 2020 14:18

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

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 98.6 °F

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

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

PC Time Stamp	16 OCT 2020 20:25
PC Open Date & Time	16 OCT 2020 15:13
PC Close Date & Time	17 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:11

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

99.7 °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 OCT 2020 19:36

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:11

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 18:43

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:11

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

19 OCT 2020 19:08

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:11

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

97.3 °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 OCT 2020 16:28

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:11

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 16:48

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:11

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

97.8 °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

22 OCT 2020 21:57

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 12:11

PC Open Date & Time

16 OCT 2020 11:48

PC Close Date & Time

16 OCT 2020 14:18

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

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

16 OCT 2020 20:26

PC Open Date & Time

16 OCT 2020 15:13

PC Close Date & Time

17 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

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 ☐

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

550

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

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

Yes ☐

No ☒

Please record - **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 OCT 2020 19:38

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

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 ☐

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

80

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

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

Yes ☐

No ☒

Please record - **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 OCT 2020 18:44

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

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 ☐

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

80

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

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

Yes ☐

No ☒

Please record - **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 OCT 2020 19:08

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:11

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

20 OCT 2020 16:28

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:11

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

21 OCT 2020 16:48

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:11

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

22 OCT 2020 21:57

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

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

No ☒

Yes ☐

PC Time stamp	16 OCT 2020 12:12
PC Open Date & Time	16 OCT 2020 11:48
PC Close Date & Time	16 OCT 2020 14:18

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

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

No ☒

Yes ☐

PC Time stamp	16 OCT 2020 20:26
PC Open Date & Time	16 OCT 2020 15:13
PC Close Date & Time	17 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

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 ☒

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 19:39
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 18:44
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

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 ☒

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 19:09
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 16:28
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 16:48
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 21:58
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3712064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712064

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712064

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712064

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:39:08

Generated On: 10 Jun 2021 09:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 NOV 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

US3712064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

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) _____

US3712064

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

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.

US3712064

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 NOV 2020
Collection time (00:00-23:59)	10:54 (24 HR)
Collection date and time (derived)	13 NOV 2020 10:54

US3712064

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:39:09

Generated On: 10 Jun 2021 09:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 NOV 2020 16:58:09
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 04:50:56
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 04:41:52
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 01:28:25

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 DEC 2020 11:23:55
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 00:01:48
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	29 DEC 2020 12:01:14
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	04 JAN 2021 07:09:12
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 18:04:56
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 04:29:40

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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

03 FEB 2021 10:47:12

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 FEB 2021 06:48:52

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 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	16 FEB 2021 12:22:53
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 <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	21 FEB 2021 15:39:00
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 MAR 2021 06:03:29

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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

07 MAR 2021 10:57:54

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 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 MAR 2021 05:41:26
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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

21 MAR 2021 05:15:13

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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

28 MAR 2021 05:00:44

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 09:03:00

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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

12 APR 2021 06:27:28

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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

18 APR 2021 06:02:42

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 APR 2021 00:26:58

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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

02 MAY 2021 17:39:10

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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

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

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 <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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 <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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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

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

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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="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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 <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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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="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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 <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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

Patient Cloud Open Date & Time	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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="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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 <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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 <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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 SEP 2021 00:01
Patient Cloud Close Date & Time	23 SEP 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 <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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 <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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

Patient Cloud Open Date & Time	14 NOV 2021 00:01
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Patient Cloud Close Date & Time	18 NOV 2021 23:59
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US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 <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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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="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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 <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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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="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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐ Yes ☐

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

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

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

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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="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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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="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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐
Yes ☐

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

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

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

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 2022 00:01
Patient Cloud Close Date & Time	30 JUN 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐ Yes ☐

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

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

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

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 <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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐ Yes ☐

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

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

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

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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°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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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="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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐ Yes ☐

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

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

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

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

Patient Cloud Open Date & Time	14 AUG 2022 00:01
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Patient Cloud Close Date & Time	18 AUG 2022 23:59
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US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2022 00:01
Patient Cloud Close Date & Time	25 AUG 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 <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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 <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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐ Yes ☐

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

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

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

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 <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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 <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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2022 00:01
Patient Cloud Close Date & Time	27 OCT 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 NOV 2022 00:01
Patient Cloud Close Date & Time	17 NOV 2022 23:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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="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"/>

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2022 23:59

US3712064

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:24:11

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		01 MAR 2021 06:03:42

US3712064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 02:29:48

Generated On: 10 Jun 2021 09:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712064

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 02:29:48

Generated On: 10 Jun 2021 09:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:15:05

Generated On: 10 Jun 2021 09:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712064

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:15:05

Generated On: 10 Jun 2021 09:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:15:05

Generated On: 10 Jun 2021 09:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712064

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:15:05

Generated On: 10 Jun 2021 09:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:15:05

Generated On: 10 Jun 2021 09:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712064

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:15:05

Generated On: 10 Jun 2021 09:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712064

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3712064

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3712064

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:11

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.

US3712064

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:11

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3712064

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3712064

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:24:11

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"/>

US3712064

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:24:11

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3712064

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 00:15:05

Generated On: 10 Jun 2021 09:24:11

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

Visit date (dd MMM yyyy)	29 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
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US3712064

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 00:15:05

Generated On: 10 Jun 2021 09:24:11

Date of updated informed consent (dd MMM yyyy) 29 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 29 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3712064

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 00:15:05

Generated On: 10 Jun 2021 09:24:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 JAN 2021

Collection time (00:00-23:59)

11:02 (24 HR)

Collection date and time (derived)

29 JAN 2021 11:02

US3712064

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 00:15:05

Generated On: 10 Jun 2021 09:24:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 JAN 2021

Collection time (00:00 - 23:59)

11:05

Collection Date and Time (derived)

29 JAN 2021 11:05

US3712064

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 22:20:05

Generated On: 10 Jun 2021 09:24:11

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 23:28:27

Generated On: 10 Jun 2021 09:24:11

AEID

Adverse event

LEFT HIP PAIN

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)

15 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)

05 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 ☐

Number of Days in ICU

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EAB) (1725)

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 23:28:27

Generated On: 10 Jun 2021 09:24:11

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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)	_____

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 18 Apr 2021 23:28:27

Generated On: 10 Jun 2021 09:24:11

AEID	USA-US068-2021-MRNA-1273-P30 1000013
Adverse event	LEFT HIP DEGENERATIVE JOINT DISEASE WITH ARTHRITIS
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)	12 JAN 2021
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)	05 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	04 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	05 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 18 Apr 2021 23:28:27

Generated On: 10 Jun 2021 09:24:11

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

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 18 Apr 2021 23:28:27

Generated On: 10 Jun 2021 09:24:11

SUBJECT REPORTED TO UPMC
ON 04 FEB 2021 FOR LEFT HIP
REPLACEMENT WITH (b) (6)
HE WAS ADMITTED TO THE
HOSPITAL OVER NIGHT FOR
ONE NIGHT AND WAS
DISCHARGED ON 05 FEB 2021.
SUBJECT REPORTED TO TOC
ON 12 JAN 2021, COMPLAINING
OF 5/10 LEFT HIP PAIN. LEFT
HIP X-RAY SHOWED A
SIGNIFICANT DEGENERATION
OF LEFT HIP WITH CYSTIC
CHANGES, LOSS OF JOINT
SPACE AND OSTEOARTHRITIS.
THERE IS ONLY ABOUT 1MM
OF JOINT SPACE REMAINING
THROUGH OUT THE HIP. ON 04
FEB 2021 SUBJECT HAD A LEFT
TOTAL HIP ARTHROPLASTY
THROUGH AN ANTERIOR
APPROACH. SPINAL
ANESTHESIA WAS USED.
BLOOD LOSS WAS MINIMAL.
MEDIUM HEMOVAC DRAIN
WAS PLACED. SUBJECT HAD
NO COMPLICATIONS AND
RECOVERED ACCORDING TO
ORTHOPEDIST'S PLAN.
SUBJECT CONTINUES TO
RECOVER WITHOUT PAIN OR
COMPLICATIONS. SUBJECT
RECEIVED NORCO
7.5MG-325MG Q4HR PRN,
ELIQUIS 2.5MG BID X 35 DAYS,

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 18 Apr 2021 23:28:27

Generated On: 10 Jun 2021 09:24:11

ZOFRAN 4MG Q12HR PRN,
DEXTROSE IN WATER IV
50ML/HR, ANCEF 2G IV X 1,
ANCEF 1G X 2,
METHYLPHENIDATE 10MG PO
X 3. LAB WORK SHOWED:
SODIUM 134, POTASSIUM 134,
CHLORIDE 98, C02 32, BUN 17,
CREATININE 0.95, CALCIUM 9.0,
HEMOGLOBIN 12.5,
HEMATOCRIT 36.2, WBC 13.1,
PLATELET 197, RBC 4.12,
GLUCOSE 159. SUBJECT WAS
DISCHARGED HOME WITHOUT
COMPLAINT ON 05 FEB 2021.

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

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 00:15:05

Generated On: 10 Jun 2021 09:24:11

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

Yes ☒

No ☐

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

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 21:39:18

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Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication RITALIN

Prophylaxis Yes ☐
No ☒

Indication ADULT ADD

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication RITALIN ER

Prophylaxis Yes ☐
No ☒

Indication ADULT ADD

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTIVE HEALTH

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)		02 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		02 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication LEFT HIP PAIN

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)		22 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication LEFT HIP REPLACEMENT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)		04 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication HYDROCODONEACETAMINOPH
EN (NORCO)

Prophylaxis Yes ☐
No ☒

Indication LEFT HIP REPLACEMENT

Dose per administration 7.5/325

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)		04 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication LEFT HIP REPLACEMENT

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)	04 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 MAR 2021
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication LEFT HIP REPLACEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)		04 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication DEXTROSE IN WATER

Prophylaxis Yes ☐
No ☒

Indication LEFT HIP REPLACEMENT

Dose per administration 50

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

If dose unit is Other, specify ML/HR

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)		04 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication ANCEF

Prophylaxis Yes ☐
No ☒

Indication LEFT 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)		04 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication ANCEF

Prophylaxis Yes ☐
No ☒

Indication LEFT HIP REPLACEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

2 DOSES

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)		04 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication METHYLPHENIDATE

Prophylaxis Yes ☐
No ☒

Indication LEFT HIP REPLACEMENT

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

3 DOSES

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)		04 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication DOCUSATE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF
CONSTIPATION WHILE
HOSPITALIZED

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)	04 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 2021
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication SENNA (SENOKOT)

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF
CONSTIPATION WHILE
HOSPITALIZED

Dose per administration 50/8.6

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)	04 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	05 FEB 2021	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF PAIN DURING
HOSPITALIZATION

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)		04 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication CHOLECALCIFEROL

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 2000

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)		04 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 2021
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication BISACODYL

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF
CONSTIPATION DURING
HOSPITALIZATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	Intraocular	<input type="radio"/>
	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	SUPPOSITORY	
Start date (dd MMM yyyy)	04 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	05 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication DIPHENHYDRAMINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF OF ALLERGIC
REACTION WHILE
HOSPITALIZED

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)		04 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication DIPHENHYDRAMINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF OF ALLERGIC
REACTION WHILE
HOSPITALIZED

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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 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)	04 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication NORMAL SALINE FLUSH

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF IV CLOTTING
WHILE HOSPITALIZED

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 12 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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 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)	04 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 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"/>

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication MAALOX SIMETHICONE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF ACID REFLUX
DURING HOSPITALIZED

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

EVERY 4 HOURS AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)	04 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication MAG-OX

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)		04 FEB 2021
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication NORMAL SALINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF
DEHYDRATION DURING
HOSPITALIZATION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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 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)	04 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	05 FEB 2021	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication NORMAL SALINE FLUSH

Prophylaxis Yes ☒
No ☐

Indication FLUSH OF IV WHILE
HOSPITALIZATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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 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)	04 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	05 FEB 2021	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication ONDANSETRON

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF NAUSEA
WHILE HOSPITALIZED

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

EVERY 6 HOURS AS NEEDED

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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 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)	04 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication PROMETHAZINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF NAUSEA
DURING HOSPITALIZATION

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

EVERY 6 HOURS AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)		04 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication PROMETHAZINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF NAUSEA
DURING HOSPITALIZATION

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

EVERY 6 HOURS AS NEEDED

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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 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)	04 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication SIMETHICONE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF PAIN WHILE
HOSPITALIZED

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 4 HOURS AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)	04 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 2000

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 23 Apr 2021 21:39:18

Generated On: 10 Jun 2021 09:24:11

	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)	04 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	05 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 18 Apr 2021 23:28:27

Generated On: 10 Jun 2021 09:24:11

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 18 Apr 2021 23:28:27

Generated On: 10 Jun 2021 09:24:11

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
04 FEB 2021	LEFT HIP REPLACEMENT	Adverse Event	
12 JAN 2021	LEFT HIP X-RAY	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:24:11

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:24:11

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 ☐

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 18 Apr 2021 23:28:28

Generated On: 10 Jun 2021 09:24:11

SAEID	USA-US068-2021-MRNA-1273-P301000013
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 18 Apr 2021 23:28:28

Generated On: 10 Jun 2021 09:24:11

SAEID	USA-US068-2021-MRNA-1273-P301000013
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/FEB/2021 14:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 18 Apr 2021 23:28:28

Generated On: 10 Jun 2021 09:24:11

SAEID	USA-US068-2021-MRNA-1273-P301000013
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	24/FEB/2021 11:17
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

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 18 Apr 2021 23:28:28

Generated On: 10 Jun 2021 09:24:11

SAEID	USA-US068-2021-MRNA-1273-P301000013
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/MAR/2021 09:53
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

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Data signed: (b) (4) 18 Apr 2021 23:28:28

Generated On: 10 Jun 2021 09:24:11

SAEID	USA-US068-2021-MRNA-1273-P301000013
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	31/MAR/2021 13:54
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Data signed: (b) (4) 18 Apr 2021 23:28:28

Generated On: 10 Jun 2021 09:24:11

SAEID	USA-US068-2021-MRNA-1273-P301000013
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	WILLIAM
Investigator's Last Name	SMITH
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	(b) (4)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	15/APR/2021 15:20
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

US3712064 (Prod: Alliance for Multispecialty Research, LLC)

US3712064

Form: Participant Creation

Generated On: 10 Jun 2021 09:24:11

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:50:03
User entered 'US3712064'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:04:33

US3712064

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 12:58:07

US3712064

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:03
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:04:34

US3712064

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

[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 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:03
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Sep 2020 12:58:07

US3712064

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'SCRN'	System	11 Sep 2020 12:58:07

US3712064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:11

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:07
User entered (b) (6) 1946'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:04:35

US3712064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:11

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:07
User entered '74'	(b) (4), (b) (6)	11 Sep 2020 13:00:36

US3712064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:11

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'YEARS'	System	11 Sep 2020 13:00:36

US3712064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '74'	System	11 Sep 2020 13:00:48

US3712064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:11

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:07
User entered 'Male (M)'	(b) (4), (b) (6)	11 Sep 2020 13:00:36

US3712064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:11

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:07
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	11 Sep 2020 13:00:36

US3712064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:11

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:07
User entered 'I'	(b) (4), (b) (6)	11 Sep 2020 13:00:36

US3712064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:11

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:07
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 13:00:36

US3712064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:11

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:07
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 13:00:36

US3712064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:07
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 13:00:36

US3712064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:07
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 13:00:36

US3712064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:07
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 13:00:36

US3712064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:11

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:07
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 13:00:36

US3712064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:11

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:07
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 13:00:36

US3712064

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:11

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:07
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 13:00:36

US3712064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:11

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:15
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 13:00:48

US3712064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Sep 2020'	System	11 Sep 2020 13:00:48

US3712064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2020'	System	11 Sep 2020 13:00:48

US3712064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:11

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:15
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	11 Sep 2020 13:00:48

US3712064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:15
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 16:48:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 10:38:01
Query 'Data is required. Please complete.' answered with 'pending randomization' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 13:00:58
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 13:00:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 13:00:48

US3712064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:15
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 13:00:48

US3712064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:15
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 13:00:48

US3712064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:15
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 13:00:48

US3712064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:15
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 13:04:34

US3712064

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:24:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'I'	System	18 Sep 2020 16:48:37

US3712064

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:41:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 16:48:37

US3712064

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:24:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:45:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:30:47

US3712064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:13:47
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 08:11:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 08:11:40
Data point term sent to Coder	System	30 Sep 2020 17:40:29
User closed query 'DM-Coding: Please provide a diagnosis/procedure for the drug reported. Please update this term in accordance with your answer.' (Site from System).	System	30 Sep 2020 17:40:24
Query 'DM-Coding: Please provide a diagnosis/procedure for the drug reported. Please update this term in accordance with your answer.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 17:40:24
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 17:40:15
User entered 'allergy to LOVENOX' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 17:40:15
User opened query 'DM-Coding: Please provide a diagnosis/procedure for the drug reported. Please update this term in accordance with your answer.' (Site from System).	Coder Import (b) (4)	25 Sep 2020 18:56:45
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 19:06:43
Data point term sent to Coder	System	18 Sep 2020 19:31:29
User entered 'lovenox'	(b) (4), (b) (6)	18 Sep 2020 19:31:19

US3712064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'un Jun 2019'	(b) (4), (b) (6)	18 Sep 2020 19:31:19

US3712064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:31:19

US3712064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:31:19

US3712064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:31:19

US3712064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:31:19

US3712064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jun 2019'	System	18 Sep 2020 19:31:19

US3712064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2019'	System	18 Sep 2020 19:31:19

US3712064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered empty.	System	18 Sep 2020 19:31:19

US3712064

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered empty.	System	18 Sep 2020 19:31:19

US3712064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Hyperopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:33:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:33:46
Data point term sent to Coder	System	18 Sep 2020 19:32:30
User entered 'hyperopia'	(b) (4), (b) (6)	18 Sep 2020 19:31:32

US3712064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'un UNK 1949'	(b) (4), (b) (6)	18 Sep 2020 19:31:32

US3712064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:31:32

US3712064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:31:32

US3712064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:31:32

US3712064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:31:32

US3712064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jan 1949'	System	18 Sep 2020 19:31:32

US3712064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '1949'	System	18 Sep 2020 19:31:32

US3712064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered empty.	System	18 Sep 2020 19:31:32

US3712064

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered empty.	System	18 Sep 2020 19:31:32

US3712064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin vascular abnormalities, HLT: Purpura and related conditions, PT: Purpura senile, LLT: Purpura senile - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:33:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:33:46
Data point term sent to Coder	System	18 Sep 2020 19:32:30
User entered 'senile purpura'	(b) (4), (b) (6)	18 Sep 2020 19:32:01

US3712064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'un UNK 2015'	(b) (4), (b) (6)	18 Sep 2020 19:32:01

US3712064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:32:01

US3712064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:32:01

US3712064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:32:01

US3712064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:32:01

US3712064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jan 2015'	System	18 Sep 2020 19:32:01

US3712064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2015'	System	18 Sep 2020 19:32:01

US3712064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered empty.	System	18 Sep 2020 19:32:01

US3712064

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered empty.	System	18 Sep 2020 19:32:01

US3712064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:33:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:33:47
Data point term sent to Coder	System	18 Sep 2020 19:32:30
User entered 'hypertension'	(b) (4), (b) (6)	18 Sep 2020 19:32:15

US3712064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'un UNK 2009'	(b) (4), (b) (6)	18 Sep 2020 19:32:15

US3712064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:32:15

US3712064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:32:15

US3712064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:32:15

US3712064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:32:15

US3712064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jan 2009'	System	18 Sep 2020 19:32:15

US3712064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2009'	System	18 Sep 2020 19:32:15

US3712064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered empty.	System	18 Sep 2020 19:32:15

US3712064

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered empty.	System	18 Sep 2020 19:32:15

US3712064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:34:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:34:40
Data point term sent to Coder	System	18 Sep 2020 19:33:31
User entered 'obstructive sleep apnea'	(b) (4), (b) (6)	18 Sep 2020 19:32:41

US3712064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'un UNK 1998'	(b) (4), (b) (6)	18 Sep 2020 19:32:41

US3712064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:32:41

US3712064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:32:41

US3712064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:32:41

US3712064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:32:41

US3712064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jan 1998'	System	18 Sep 2020 19:32:41

US3712064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '1998'	System	18 Sep 2020 19:32:41

US3712064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered empty.	System	18 Sep 2020 19:32:41

US3712064

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered empty.	System	18 Sep 2020 19:32:41

US3712064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:24:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:14:38
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User closed query 'Per DM CLR: Please update the condition to confirm if the COLON POLYPS were benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:20:21
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Benign colonic polyp - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:51:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:51:22
Query 'Per DM CLR: Please update the condition to confirm if the COLON POLYPS were benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 19:29:20
Data point term sent to Coder	System	14 Oct 2020 19:29:07
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 19:29:07
Coding entries removed.	(b) (4), (b) (6)	14 Oct 2020 19:29:07
User entered 'COLON POLYPS (benign)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 19:29:07
User opened query 'Per DM CLR: Please update the condition to confirm if the COLON POLYPS were benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:18:01
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 19:06:43

US3712064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:24:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Colonic polyp - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:34:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:34:39
Data point term sent to Coder	System	18 Sep 2020 19:33:37
User entered 'colon polyps'	(b) (4), (b) (6)	18 Sep 2020 19:33:20

US3712064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'un UNK 2012'	(b) (4), (b) (6)	18 Sep 2020 19:33:20

US3712064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:33:20

US3712064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:33:20

US3712064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:33:20

US3712064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:33:20

US3712064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jan 2012'	System	18 Sep 2020 19:33:20

US3712064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2012'	System	18 Sep 2020 19:33:20

US3712064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered empty.	System	18 Sep 2020 19:33:20

US3712064

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered empty.	System	18 Sep 2020 19:33:20

US3712064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:24:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Left inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:35:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:35:39
Data point term sent to Coder	System	18 Sep 2020 19:34:41
User entered 'left inguinal hernia'	(b) (4), (b) (6)	18 Sep 2020 19:34:23

US3712064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '13 May 2020'	(b) (4), (b) (6)	18 Sep 2020 19:34:23

US3712064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:34:23

US3712064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:34:23

US3712064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '13 May 2020'	(b) (4), (b) (6)	18 Sep 2020 19:34:23

US3712064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:34:23

US3712064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'May 2020'	System	18 Sep 2020 19:34:23

US3712064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2020'	System	18 Sep 2020 19:34:23

US3712064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'May 2020'	System	18 Sep 2020 19:34:23

US3712064

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2020'	System	18 Sep 2020 19:34:23

US3712064

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:24:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal hernia repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:36:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:36:42
Data point term sent to Coder	System	18 Sep 2020 19:35:44
User entered 'left inguinal hernia repair'	(b) (4), (b) (6)	18 Sep 2020 19:34:45

US3712064

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '13 May 2020'	(b) (4), (b) (6)	18 Sep 2020 19:34:45

US3712064

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:34:45

US3712064

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:34:45

US3712064

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '13 May 2020'	(b) (4), (b) (6)	18 Sep 2020 19:34:45

US3712064

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:34:45

US3712064

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'May 2020'	System	18 Sep 2020 19:34:45

US3712064

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2020'	System	18 Sep 2020 19:34:45

US3712064

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'May 2020'	System	18 Sep 2020 19:34:45

US3712064

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2020'	System	18 Sep 2020 19:34:45

US3712064

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:24:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:36:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:36:44
Data point term sent to Coder	System	18 Sep 2020 19:35:44
User entered 'prostate cancer'	(b) (4), (b) (6)	18 Sep 2020 19:35:25

US3712064

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'un UNK 2005'	(b) (4), (b) (6)	18 Sep 2020 19:35:25

US3712064

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:35:25

US3712064

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:35:25

US3712064

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:18:33
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please confirm since a procedure for this condition (MH# 15) was reported (UN UNK 2005-UN UNK 2005). Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:07:42
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please confirm since a procedure for this condition (MH# 15) was reported (UN UNK 2005-UN UNK 2005). Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 12:59:59
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 12:59:52
User entered 'UN UNK 2005' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 12:59:52
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. Please confirm since a procedure for this condition (MH# 15) was reported (UN UNK 2005-UN UNK 2005). Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:18:55
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'un UNK 2010'	(b) (4), (b) (6)	18 Sep 2020 19:35:25

US3712064

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:35:25

US3712064

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jan 2005'	System	18 Sep 2020 19:35:25

US3712064

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2005'	System	18 Sep 2020 19:35:25

US3712064

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jan 2005'	System	14 Oct 2020 12:59:52
User entered 'Jan 2010'	System	18 Sep 2020 19:35:25

US3712064

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2005'	System	14 Oct 2020 12:59:52
User entered '2010'	System	18 Sep 2020 19:35:25

US3712064

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:24:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Renal and urinary tract neoplasms malignant and unspecified, HLT: Bladder neoplasms malignant, PT: Bladder cancer, LLT: Bladder cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:36:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:36:43
Data point term sent to Coder	System	18 Sep 2020 19:35:45
User entered 'bladder cancer'	(b) (4), (b) (6)	18 Sep 2020 19:35:44

US3712064

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'un UNK 2014'	(b) (4), (b) (6)	18 Sep 2020 19:35:44

US3712064

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:35:44

US3712064

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:35:44

US3712064

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'un UNK 2014'	(b) (4), (b) (6)	18 Sep 2020 19:35:44

US3712064

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:35:44

US3712064

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jan 2014'	System	18 Sep 2020 19:35:44

US3712064

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2014'	System	18 Sep 2020 19:35:44

US3712064

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jan 2014'	System	18 Sep 2020 19:35:44

US3712064

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2014'	System	18 Sep 2020 19:35:44

US3712064

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:24:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:08:52
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'added' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:03:12
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:19:40
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 19:06:43
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 arthroplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:38:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:38:36
Data point term sent to Coder	System	18 Sep 2020 19:37:49
User entered 'total hip arthroplasty'	(b) (4), (b) (6)	18 Sep 2020 19:36:59

US3712064

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'un Jun 2019'	(b) (4), (b) (6)	18 Sep 2020 19:36:59

US3712064

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:36:59

US3712064

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:36:59

US3712064

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	18 Sep 2020 19:37:09
User entered 'UN Jun 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 19:37:09
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	18 Sep 2020 19:36:59
User entered 'un UNK 2019'	(b) (4), (b) (6)	18 Sep 2020 19:36:59

US3712064

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:36:59

US3712064

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jun 2019'	System	18 Sep 2020 19:36:59

US3712064

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2019'	System	18 Sep 2020 19:36:59

US3712064

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jun 2019'	System	18 Sep 2020 19:37:09
User entered 'Jan 2019'	System	18 Sep 2020 19:36:59

US3712064

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2019'	System	18 Sep 2020 19:36:59

US3712064

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:24:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:38:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:38:36
Data point term sent to Coder	System	18 Sep 2020 19:37:51
User entered 'bilateral knees osteoarthritis'	(b) (4), (b) (6)	18 Sep 2020 19:37:42

US3712064

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'un UNK 2010'	(b) (4), (b) (6)	18 Sep 2020 19:37:42

US3712064

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:37:42

US3712064

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:37:42

US3712064

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:37:42

US3712064

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:37:42

US3712064

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jan 2010'	System	18 Sep 2020 19:37:42

US3712064

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2010'	System	18 Sep 2020 19:37:42

US3712064

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered empty.	System	18 Sep 2020 19:37:42

US3712064

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered empty.	System	18 Sep 2020 19:37:42

US3712064

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:24:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:39:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:39:38
Data point term sent to Coder	System	18 Sep 2020 19:38:53
User entered 'sciatica'	(b) (4), (b) (6)	18 Sep 2020 19:38:04

US3712064

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'un Dec 2015'	(b) (4), (b) (6)	18 Sep 2020 19:38:04

US3712064

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:38:04

US3712064

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:38:04

US3712064

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:38:04

US3712064

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:38:04

US3712064

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Dec 2015'	System	18 Sep 2020 19:38:04

US3712064

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2015'	System	18 Sep 2020 19:38:04

US3712064

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered empty.	System	18 Sep 2020 19:38:04

US3712064

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered empty.	System	18 Sep 2020 19:38:04

US3712064

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:24:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:18:53
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User closed query 'Per MM, please expand the abbreviation ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:24:50
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 13:05:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 13:05:26
Data point term sent to Coder	System	14 Oct 2020 13:04:18
Query 'Per MM, please expand the abbreviation ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:03:44
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 13:03:39
Coding entries removed.	(b) (4), (b) (6)	14 Oct 2020 13:03:39
User entered 'ADULT Attention deficit disorder' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 13:03:39
User opened query 'Per MM, please expand the abbreviation ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 00:55:07
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 19:06:43
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: ADD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 04:29:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 04:29:39
Data point term sent to Coder	System	18 Sep 2020 19:38:54
User entered 'adult add'	(b) (4), (b) (6)	18 Sep 2020 19:38:23

US3712064

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'un UNK 2015'	(b) (4), (b) (6)	18 Sep 2020 19:38:23

US3712064

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:38:23

US3712064

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:38:23

US3712064

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:38:23

US3712064

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:38:23

US3712064

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jan 2015'	System	18 Sep 2020 19:38:23

US3712064

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2015'	System	18 Sep 2020 19:38:23

US3712064

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered empty.	System	18 Sep 2020 19:38:23

US3712064

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered empty.	System	18 Sep 2020 19:38:23

US3712064

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:24:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Prostatic therapeutic procedures, PT: Radical prostatectomy, LLT: Radical prostatectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:40:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:40:40
Data point term sent to Coder	System	18 Sep 2020 19:39:56
User entered 'radical prostatectomy'	(b) (4), (b) (6)	18 Sep 2020 19:39:07

US3712064

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'un UNK 2005'	(b) (4), (b) (6)	18 Sep 2020 19:39:07

US3712064

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:39:07

US3712064

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:39:07

US3712064

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'un UNK 2005'	(b) (4), (b) (6)	18 Sep 2020 19:39:07

US3712064

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:39:07

US3712064

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jan 2005'	System	18 Sep 2020 19:39:07

US3712064

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2005'	System	18 Sep 2020 19:39:07

US3712064

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jan 2005'	System	18 Sep 2020 19:39:07

US3712064

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2005'	System	18 Sep 2020 19:39:07

US3712064

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:24:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:19:12
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User coded data point as SOC: Investigations, HLGT: Renal and urinary tract investigations and urinalyses, HLT: Urinary tract imaging procedures, PT: Cystoscopy, LLT: Cystoscopy - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 12:17:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 12:17:37
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 19:20:50
Data point term sent to Coder	System	14 Oct 2020 13:05:18
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:04:39
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 13:04:34
Coding entries removed.	(b) (4), (b) (6)	14 Oct 2020 13:04:34
User entered 'CYSTOSCOPY of the bladder' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 13:04:34
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:20:27
DataPoint Verified.	(b) (4), (b) (6)	24 Sep 2020 19:06:43
User coded data point as SOC: Investigations, HLGT: Renal and urinary tract investigations and urinalyses, HLT: Urinary tract imaging procedures, PT: Cystoscopy, LLT: Cystoscopy - version MedDRA\23.0.	Coder Import (b) (4)	18 Sep 2020 19:40:41

US3712064

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:24:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	18 Sep 2020 19:40:41
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 19:39:58
User entered 'cystoscopy'	(b) (4), (b) (6)	18 Sep 2020 19:39:33

US3712064

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'un UNK 2014'	(b) (4), (b) (6)	18 Sep 2020 19:39:33

US3712064

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:39:33

US3712064

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:39:33

US3712064

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered 'un UNK 2014'	(b) (4), (b) (6)	18 Sep 2020 19:39:33

US3712064

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:06:43
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:39:33

US3712064

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jan 2014'	System	18 Sep 2020 19:39:33

US3712064

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2014'	System	18 Sep 2020 19:39:33

US3712064

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jan 2014'	System	18 Sep 2020 19:39:33

US3712064

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2014'	System	18 Sep 2020 19:39:33

US3712064

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:24:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:20:46
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
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)	14 Oct 2020 13:04:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 13:04:35
Data point term sent to Coder	System	14 Oct 2020 13:03:17
User entered 'osteoarthritis in right hip'	(b) (4), (b) (6)	14 Oct 2020 13:02:24

US3712064

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:20:46
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'un Jun 2019'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:02:24

US3712064

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:20:46
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:02:24

US3712064

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:20:46
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:02:24

US3712064

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:20:46
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
Query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:09:14
User opened query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 03:18:49
User entered 'un Jun 2019'	(b) (4), (b) (6)	14 Oct 2020 13:02:24

US3712064

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:20:46
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:02:24

US3712064

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jun 2019'	System	14 Oct 2020 13:02:24

US3712064

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2019'	System	14 Oct 2020 13:02:24

US3712064

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'Jun 2019'	System	14 Oct 2020 13:02:24

US3712064

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '2019'	System	14 Oct 2020 13:02:24

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:09:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:28:35

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:09:58
User entered '10 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 19:28:35

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:09:58
User entered '09:39'	(b) (4), (b) (6)	18 Sep 2020 19:28:35

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '10 Sep 2020 09:39'	System	18 Sep 2020 19:28:35

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:09:58
User entered '182.8' cm	(b) (4), (b) (6)	18 Sep 2020 19:28:35
DataPoint set to visible.	System	18 Sep 2020 16:48:37

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:09:58
User entered '94.8' kg	(b) (4), (b) (6)	18 Sep 2020 19:28:35
DataPoint set to visible.	System	18 Sep 2020 16:48:37

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered '28.36978'	System	18 Sep 2020 19:28:35
DataPoint set to visible.	System	18 Sep 2020 16:48:37

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'kg/m2'	System	18 Sep 2020 19:28:35
DataPoint set to visible.	System	18 Sep 2020 16:48:37

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:09:58
User entered '36.8' C	(b) (4), (b) (6)	18 Sep 2020 19:28:35

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:09:58
User entered 'Oral (Oral)'	(b) (4), (b) (6)	18 Sep 2020 19:28:35

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:09:58
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:28:35

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:09:58
User entered '70'	(b) (4), (b) (6)	18 Sep 2020 19:28:35

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'bpm'	System	18 Sep 2020 19:28:35

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:09:58
User entered '16'	(b) (4), (b) (6)	18 Sep 2020 19:28:35

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'breaths/min'	System	18 Sep 2020 19:28:35

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:09:58
User entered '131'	(b) (4), (b) (6)	18 Sep 2020 19:28:35

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'mmHg'	System	18 Sep 2020 19:28:35

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:09:58
User entered '84'	(b) (4), (b) (6)	18 Sep 2020 19:28:35

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User entered 'mmHg'	System	18 Sep 2020 19:28:35

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02

US3712064

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02

US3712064

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:10:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:28:44

US3712064

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:10:22
User entered '10 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 19:28:44

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

[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 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

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 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

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 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

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 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

[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 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

[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 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

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 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

[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 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

[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 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

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 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

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 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered 'worship, restaurants, grocery shopping'	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

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 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

[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 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

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 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 01:01:02
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:19:53
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:30:39

US3712064

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:55:08
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:43:57

US3712064

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:55:08
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:43:57

US3712064

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:55:08
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:43:57

US3712064

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered 'VISIT1'	System	18 Sep 2020 19:43:57

US3712064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:08:08
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '18 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 15:39:19

US3712064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:11

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:08:08
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '191109'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 15:39:19

US3712064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:11

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:08:08
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 15:39:19

US3712064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:11

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)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:08:08
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:49:37

US3712064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:11

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)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:08:08
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:49:37

US3712064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:11

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:08:08
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:49:37

US3712064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:11

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:08:08
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:49:37

US3712064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:11

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:08:08
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:49:37

US3712064

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:11

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:08:08
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:31:20
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:55:40
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:55:38

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '182.5' cm	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '94.6' kg	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '182.5' cm	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '94.6' kg	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '10:45'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered '18 Sep 2020 10:45'	System	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '64'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered 'bpm'	System	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '16'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered 'breaths/min'	System	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '142'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered 'mmHg'	System	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '87'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered 'mmHg'	System	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '182.5' cm	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '94.6' kg	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '13:10'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered '18 Sep 2020 13:10'	System	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '78'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered 'bpm'	System	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '16'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered 'breaths/min'	System	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '133'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered 'mmHg'	System	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:41
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '86'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered 'mmHg'	System	18 Sep 2020 19:45:03

US3712064

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:58
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:31:38

US3712064

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:09:58
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:31:38

US3712064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:10:21
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:49:58

US3712064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:10:21
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:49:58

US3712064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

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)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:10:21
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:49:58

US3712064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 16:49:58

US3712064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:10:21
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:49:58

US3712064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:10:21
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '12:40'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:49:58

US3712064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered '18 Sep 2020 12:40'	System	18 Sep 2020 16:49:58

US3712064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:10:21
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:49:58

US3712064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:10:21
User entered 'ONCE'	System	18 Sep 2020 16:49:58

US3712064

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 16:49:58

US3712064

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:10:57
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:15

US3712064

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:10:57
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:15

US3712064

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:10:57
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '10:49'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:15

US3712064

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered '18 Sep 2020 10:49'	System	18 Sep 2020 19:45:15

US3712064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:11:10
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:25

US3712064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	18 Sep 2020 19:45:25

US3712064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:11:10
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:25

US3712064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:11

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:11:10
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '10:54'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:25

US3712064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered '18 Sep 2020 10:54'	System	18 Sep 2020 19:45:25

US3712064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	18 Sep 2020 19:45:25

US3712064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:11:10
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:10:35
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:32:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 20:32:33
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:25

US3712064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:11:10
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:10:35
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:32:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 20:32:33
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '10:54'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:45:25

US3712064

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered empty.	System	15 Feb 2021 20:32:33
User entered '18 Sep 2020 10:54'	System	18 Sep 2020 19:45:25

US3712064

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:11:15
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:50:28

US3712064

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered 'I'	System	18 Sep 2020 16:50:28

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T13:07:56', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '12cf35ac-ae35-49d2-8bba-20bddd6d075f' User entered 'Yes (Y)'	System	18 Sep 2020 17:08:52
	System	18 Sep 2020 17:08:52

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T13:08:34', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '12cf35ac-ae35-49d2-8bba-20bddd6d075f' User entered '98.4'	System	18 Sep 2020 17:08:52
	System	18 Sep 2020 17:08:52

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T13:08:40', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '12cf35ac-ae35-49d2-8bba-20bddd6d075f' User entered 'No (N)'	System	18 Sep 2020 17:08:52
	System	18 Sep 2020 17:08:52

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T13:08:50', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '12cf35ac-ae35-49d2-8bba-20bddd6d075f' User entered '18 Sep 2020 13:08'	System	18 Sep 2020 17:08:52
	System	18 Sep 2020 17:08:52

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '18 Sep 2020 13:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '18 Sep 2020 15:30'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T20:15:58', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'ad9e8b3b-5a1d-456e-911a-1d8cfc811036'	System	19 Sep 2020 00:19:36
User entered 'Yes (Y)'	System	19 Sep 2020 00:19:36

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T20:19:17', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'ad9e8b3b-5a1d-456e-911a-1d8cfc811036' User entered '97.2'	System	19 Sep 2020 00:19:36
	System	19 Sep 2020 00:19:36

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T20:19:20', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'ad9e8b3b-5a1d-456e-911a-1d8cfc811036'	System	19 Sep 2020 00:19:36
User entered 'No (N)'	System	19 Sep 2020 00:19:36

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T20:19:32', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'ad9e8b3b-5a1d-456e-911a-1d8cfc811036'	System	19 Sep 2020 00:19:36
User entered '18 Sep 2020 20:19'	System	19 Sep 2020 00:19:36

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '18 Sep 2020 16:25'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 2'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-19T20:40:16', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '4c3ac2c1-5a9e-45d9-98a5-e58392db1751' User entered 'Yes (Y)'	System	20 Sep 2020 00:42:20
	System	20 Sep 2020 00:42:20

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-19T20:41:57', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '4c3ac2c1-5a9e-45d9-98a5-e58392db1751' User entered '97.8'	System	20 Sep 2020 00:42:20
	System	20 Sep 2020 00:42:20

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-19T20:42:12', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '4c3ac2c1-5a9e-45d9-98a5-e58392db1751'	System	20 Sep 2020 00:42:20
User entered 'No (N)'	System	20 Sep 2020 00:42:20

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-19T20:42:16', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '4c3ac2c1-5a9e-45d9-98a5-e58392db1751' User entered '19 Sep 2020 20:42'	System	20 Sep 2020 00:42:20
	System	20 Sep 2020 00:42:20

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 3'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-20T21:03:12', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'ced326ac-50a4-4922-b15f-ea0b3ac673e5' User entered 'Yes (Y)'	System	21 Sep 2020 01:04:15
	System	21 Sep 2020 01:04:15

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-20T21:04:04', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'ced326ac-50a4-4922-b15f-ea0b3ac673e5' User entered '98.0'	System	21 Sep 2020 01:04:15
	System	21 Sep 2020 01:04:15

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-20T21:04:08', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'ced326ac-50a4-4922-b15f-ea0b3ac673e5'	System	21 Sep 2020 01:04:15
User entered 'No (N)'	System	21 Sep 2020 01:04:15

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-20T21:04:13', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'ced326ac-50a4-4922-b15f-ea0b3ac673e5' User entered '20 Sep 2020 21:04'	System	21 Sep 2020 01:04:15
	System	21 Sep 2020 01:04:15

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 4'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-21T20:32:04', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '11ce4e37-60c8-4af9-bf33-95e3648d8122'	System	22 Sep 2020 00:33:03
User entered 'Yes (Y)'	System	22 Sep 2020 00:33:03

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-21T20:32:53', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '11ce4e37-60c8-4af9-bf33-95e3648d8122' User entered '98.7'	System	22 Sep 2020 00:33:03
	System	22 Sep 2020 00:33:03

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-21T20:32:57', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '11ce4e37-60c8-4af9-bf33-95e3648d8122'	System	22 Sep 2020 00:33:03
User entered 'No (N)'	System	22 Sep 2020 00:33:03

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-21T20:33:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '11ce4e37-60c8-4af9-bf33-95e3648d8122' User entered '21 Sep 2020 20:33'	System	22 Sep 2020 00:33:03
	System	22 Sep 2020 00:33:03

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 5'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-22T18:59:03', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'be93561b-2344-4223-8635-c4fb0f1dbb9b' User entered 'Yes (Y)'	System	22 Sep 2020 22:59:18
	System	22 Sep 2020 22:59:18

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-22T18:59:09', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'be93561b-2344-4223-8635-c4fb0f1dbb9b' User entered '97.6'	System	22 Sep 2020 22:59:18
	System	22 Sep 2020 22:59:18

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-22T18:59:12', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'be93561b-2344-4223-8635-c4fb0f1dbb9b' User entered 'No (N)'	System	22 Sep 2020 22:59:18
	System	22 Sep 2020 22:59:18

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-22T18:59:16', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'be93561b-2344-4223-8635-c4fb0f1dbb9b' User entered '22 Sep 2020 18:59'	System	22 Sep 2020 22:59:18
	System	22 Sep 2020 22:59:18

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 6'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-23T20:39:10', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '88141eb7-35a7-4afe-8e29-d38763d06772'	System	24 Sep 2020 00:39:31
User entered 'Yes (Y)'	System	24 Sep 2020 00:39:31

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-23T20:39:21', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '88141eb7-35a7-4afe-8e29-d38763d06772' User entered '98.1'	System	24 Sep 2020 00:39:31
	System	24 Sep 2020 00:39:31

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-23T20:39:24', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '88141eb7-35a7-4afe-8e29-d38763d06772'	System	24 Sep 2020 00:39:31
User entered 'No (N)'	System	24 Sep 2020 00:39:31

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-23T20:39:28', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '88141eb7-35a7-4afe-8e29-d38763d06772'	System	24 Sep 2020 00:39:31
User entered '23 Sep 2020 20:39'	System	24 Sep 2020 00:39:31

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 7'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-24T14:14:12', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '4360f2ac-5931-4b90-8d89-432fffe69e42' User entered 'Yes (Y)'	System	24 Sep 2020 18:15:08
	System	24 Sep 2020 18:15:08

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-24T14:14:59', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '4360f2ac-5931-4b90-8d89-432fffe69e42' User entered '98.6'	System	24 Sep 2020 18:15:08
	System	24 Sep 2020 18:15:08

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-24T14:15:02', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '4360f2ac-5931-4b90-8d89-432fffe69e42'	System	24 Sep 2020 18:15:08
User entered 'No (N)'	System	24 Sep 2020 18:15:08

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-24T14:15:06', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '4360f2ac-5931-4b90-8d89-432fffe69e42'	System	24 Sep 2020 18:15:08
User entered '24 Sep 2020 14:15'	System	24 Sep 2020 18:15:08

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T13:09:23', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '1c6c26e4-bee5-4376-b29f-13985d4c027d' User entered 'None (1)'	System	18 Sep 2020 17:09:56
	System	18 Sep 2020 17:09:56

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T13:09:32', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '1c6c26e4-bee5-4376-b29f-13985d4c027d' User entered 'No (N)'	System	18 Sep 2020 17:09:56
	System	18 Sep 2020 17:09:56

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T13:09:37', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '1c6c26e4-bee5-4376-b29f-13985d4c027d' User entered 'No (N)'	System	18 Sep 2020 17:09:56
	System	18 Sep 2020 17:09:56

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T13:09:47', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '1c6c26e4-bee5-4376-b29f-13985d4c027d' User entered 'None (1)'	System	18 Sep 2020 17:09:56
	System	18 Sep 2020 17:09:56

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T13:09:53', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '1c6c26e4-bee5-4376-b29f-13985d4c027d' User entered '18 Sep 2020 13:09'	System	18 Sep 2020 17:09:56
	System	18 Sep 2020 17:09:56

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '18 Sep 2020 13:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '18 Sep 2020 15:30'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T20:19:38', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5a843e10-268d-42e8-8e67-be26c823c808' User entered 'None (1)'	System	19 Sep 2020 00:19:57
	System	19 Sep 2020 00:19:57

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T20:19:42', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5a843e10-268d-42e8-8e67-be26c823c808' User entered 'No (N)'	System	19 Sep 2020 00:19:57
	System	19 Sep 2020 00:19:57

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T20:19:44', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5a843e10-268d-42e8-8e67-be26c823c808' User entered 'No (N)'	System	19 Sep 2020 00:19:57
	System	19 Sep 2020 00:19:57

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T20:19:48', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5a843e10-268d-42e8-8e67-be26c823c808' User entered 'None (1)'	System	19 Sep 2020 00:19:57
	System	19 Sep 2020 00:19:57

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T20:19:52', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5a843e10-268d-42e8-8e67-be26c823c808' User entered '18 Sep 2020 20:19'	System	19 Sep 2020 00:19:57
	System	19 Sep 2020 00:19:57

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '18 Sep 2020 16:25'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 2'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-19T20:42:25', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '1eaadbcf-bbe5-40ae-96a9-bcdfa3ec3c1d'	System	20 Sep 2020 00:42:46
User entered 'Does not interfere with activity (2)'	System	20 Sep 2020 00:42:46

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-19T20:42:29', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '1eaadbcf-bbe5-40ae-96a9-bcdfa3ec3c1d' User entered 'No (N)'	System	20 Sep 2020 00:42:46
	System	20 Sep 2020 00:42:46

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-19T20:42:33', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '1eaadbcf-bbe5-40ae-96a9-bcdfa3ec3c1d' User entered 'No (N)'	System	20 Sep 2020 00:42:46
	System	20 Sep 2020 00:42:46

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-19T20:42:40', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '1eaadbcf-bbe5-40ae-96a9-bcdfa3ec3c1d' User entered 'None (1)'	System	20 Sep 2020 00:42:46
	System	20 Sep 2020 00:42:46

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-19T20:42:43', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '1eaadbcf-bbe5-40ae-96a9-bcdfa3ec3c1d' User entered '19 Sep 2020 20:42'	System	20 Sep 2020 00:42:46
	System	20 Sep 2020 00:42:46

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 3'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-20T21:04:18', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f13d7f89-ee01-4227-9d45-4a5c4cd309de' User entered 'None (1)'	System	21 Sep 2020 01:04:37
	System	21 Sep 2020 01:04:37

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-20T21:04:21', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f13d7f89-ee01-4227-9d45-4a5c4cd309de' User entered 'No (N)'	System	21 Sep 2020 01:04:37
	System	21 Sep 2020 01:04:37

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-20T21:04:24', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f13d7f89-ee01-4227-9d45-4a5c4cd309de' User entered 'No (N)'	System	21 Sep 2020 01:04:37
	System	21 Sep 2020 01:04:37

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-20T21:04:27', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f13d7f89-ee01-4227-9d45-4a5c4cd309de' User entered 'None (1)'	System	21 Sep 2020 01:04:37
	System	21 Sep 2020 01:04:37

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-20T21:04:33', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f13d7f89-ee01-4227-9d45-4a5c4cd309de' User entered '20 Sep 2020 21:04'	System	21 Sep 2020 01:04:37
	System	21 Sep 2020 01:04:37

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 4'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-21T20:33:04', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f296d8bd-6166-4456-9847-79100b52f420' User entered 'None (1)'	System	22 Sep 2020 00:33:22
	System	22 Sep 2020 00:33:22

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-21T20:33:08', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f296d8bd-6166-4456-9847-79100b52f420' User entered 'No (N)'	System	22 Sep 2020 00:33:22
	System	22 Sep 2020 00:33:22

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-21T20:33:11', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f296d8bd-6166-4456-9847-79100b52f420' User entered 'No (N)'	System	22 Sep 2020 00:33:22
	System	22 Sep 2020 00:33:22

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-21T20:33:16', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f296d8bd-6166-4456-9847-79100b52f420'	System	22 Sep 2020 00:33:22
User entered 'None (1)'	System	22 Sep 2020 00:33:22

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-21T20:33:18', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f296d8bd-6166-4456-9847-79100b52f420' User entered '21 Sep 2020 20:33'	System	22 Sep 2020 00:33:22
	System	22 Sep 2020 00:33:22

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 5'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-22T18:59:20', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '1f2d1873-5712-4566-bbaf-ec5c3963e698'	System	22 Sep 2020 22:59:40
User entered 'None (1)'	System	22 Sep 2020 22:59:40

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-22T18:59:25', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '1f2d1873-5712-4566-bbaf-ec5c3963e698'	System	22 Sep 2020 22:59:40
User entered 'No (N)'	System	22 Sep 2020 22:59:40

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-22T18:59:28', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '1f2d1873-5712-4566-bbaf-ec5c3963e698' User entered 'No (N)'	System	22 Sep 2020 22:59:40
	System	22 Sep 2020 22:59:40

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-22T18:59:32', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '1f2d1873-5712-4566-bbaf-ec5c3963e698'	System	22 Sep 2020 22:59:40
User entered 'None (1)'	System	22 Sep 2020 22:59:40

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-22T18:59:36', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '1f2d1873-5712-4566-bbaf-ec5c3963e698'	System	22 Sep 2020 22:59:40
User entered '22 Sep 2020 18:59'	System	22 Sep 2020 22:59:40

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 6'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-23T20:39:39', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '54b3c261-521a-499d-92b4-cb42d2b47ab9'	System	24 Sep 2020 00:39:52
User entered 'None (1)'	System	24 Sep 2020 00:39:52

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-23T20:39:43', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '54b3c261-521a-499d-92b4-cb42d2b47ab9'	System	24 Sep 2020 00:39:52
User entered 'No (N)'	System	24 Sep 2020 00:39:52

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-23T20:39:45', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '54b3c261-521a-499d-92b4-cb42d2b47ab9'	System	24 Sep 2020 00:39:52
User entered 'No (N)'	System	24 Sep 2020 00:39:52

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-23T20:39:48', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '54b3c261-521a-499d-92b4-cb42d2b47ab9'	System	24 Sep 2020 00:39:52
User entered 'None (1)'	System	24 Sep 2020 00:39:52

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-23T20:39:50', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '54b3c261-521a-499d-92b4-cb42d2b47ab9'	System	24 Sep 2020 00:39:52
User entered '23 Sep 2020 20:39'	System	24 Sep 2020 00:39:52

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 7'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-24T14:15:10', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '234600bd-c0d4-4d80-bf79-bc39a055d549' User entered 'None (1)'	System	24 Sep 2020 18:15:23
	System	24 Sep 2020 18:15:23

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-24T14:15:12', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '234600bd-c0d4-4d80-bf79-bc39a055d549' User entered 'No (N)'	System	24 Sep 2020 18:15:23
	System	24 Sep 2020 18:15:23

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-24T14:15:15', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '234600bd-c0d4-4d80-bf79-bc39a055d549' User entered 'No (N)'	System	24 Sep 2020 18:15:23
	System	24 Sep 2020 18:15:23

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-24T14:15:18', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '234600bd-c0d4-4d80-bf79-bc39a055d549' User entered 'None (1)'	System	24 Sep 2020 18:15:23
	System	24 Sep 2020 18:15:23

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-24T14:15:21', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '234600bd-c0d4-4d80-bf79-bc39a055d549' User entered '24 Sep 2020 14:15'	System	24 Sep 2020 18:15:23
	System	24 Sep 2020 18:15:23

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T13:10:02', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '780068ec-b575-48e2-abaa-ed7f4f52980c' User entered 'None (0)'	System	18 Sep 2020 17:11:26
	System	18 Sep 2020 17:11:26

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T13:10:06', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '780068ec-b575-48e2-abaa-ed7f4f52980c' User entered 'None (0)'	System	18 Sep 2020 17:11:26
	System	18 Sep 2020 17:11:26

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T13:10:10', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '780068ec-b575-48e2-abaa-ed7f4f52980c' User entered 'None (0)'	System	18 Sep 2020 17:11:26
	System	18 Sep 2020 17:11:26

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T13:10:14', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '780068ec-b575-48e2-abaa-ed7f4f52980c' User entered 'None (0)'	System	18 Sep 2020 17:11:26
	System	18 Sep 2020 17:11:26

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T13:10:18', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '780068ec-b575-48e2-abaa-ed7f4f52980c' User entered 'None (0)'	System	18 Sep 2020 17:11:26
	System	18 Sep 2020 17:11:26

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T13:10:21', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '780068ec-b575-48e2-abaa-ed7f4f52980c' User entered 'None (0)'	System	18 Sep 2020 17:11:26
	System	18 Sep 2020 17:11:26

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

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)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T13:10:33', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '780068ec-b575-48e2-abaa-ed7f4f52980c' User entered 'No (N)'	System	18 Sep 2020 17:11:26
	System	18 Sep 2020 17:11:26

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T13:11:24', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '780068ec-b575-48e2-abaa-ed7f4f52980c' User entered '18 Sep 2020 13:11'	System	18 Sep 2020 17:11:26
	System	18 Sep 2020 17:11:26

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '18 Sep 2020 13:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '18 Sep 2020 15:30'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T20:19:57', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'e9529220-d9d9-4132-8689-0d6beb8d0677' User entered 'None (0)'	System	19 Sep 2020 00:20:20
	System	19 Sep 2020 00:20:20

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T20:20:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'e9529220-d9d9-4132-8689-0d6beb8d0677' User entered 'None (0)'	System	19 Sep 2020 00:20:20
	System	19 Sep 2020 00:20:20

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T20:20:03', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'e9529220-d9d9-4132-8689-0d6beb8d0677' User entered 'None (0)'	System	19 Sep 2020 00:20:20
	System	19 Sep 2020 00:20:20

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T20:20:06', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'e9529220-d9d9-4132-8689-0d6beb8d0677' User entered 'None (0)'	System	19 Sep 2020 00:20:20
	System	19 Sep 2020 00:20:20

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T20:20:08', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'e9529220-d9d9-4132-8689-0d6beb8d0677' User entered 'None (0)'	System	19 Sep 2020 00:20:20
	System	19 Sep 2020 00:20:20

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T20:20:11', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'e9529220-d9d9-4132-8689-0d6beb8d0677' User entered 'None (0)'	System	19 Sep 2020 00:20:20
	System	19 Sep 2020 00:20:20

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

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)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T20:20:15', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'e9529220-d9d9-4132-8689-0d6beb8d0677'	System	19 Sep 2020 00:20:20
User entered 'No (N)'	System	19 Sep 2020 00:20:20

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-18T20:20:18', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'e9529220-d9d9-4132-8689-0d6beb8d0677' User entered '18 Sep 2020 20:20'	System	19 Sep 2020 00:20:20
	System	19 Sep 2020 00:20:20

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '18 Sep 2020 16:25'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 2'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-19T20:42:48', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '3e21a2ed-13c7-4213-88fe-4992027bcd5f' User entered 'None (0)'	System	20 Sep 2020 00:43:23
	System	20 Sep 2020 00:43:23

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-19T20:42:54', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '3e21a2ed-13c7-4213-88fe-4992027bcd5f' User entered 'None (0)'	System	20 Sep 2020 00:43:23
	System	20 Sep 2020 00:43:23

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-19T20:42:58', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '3e21a2ed-13c7-4213-88fe-4992027bcd5f' User entered 'None (0)'	System	20 Sep 2020 00:43:23
	System	20 Sep 2020 00:43:23

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-19T20:43:02', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '3e21a2ed-13c7-4213-88fe-4992027bcd5f' User entered 'None (0)'	System	20 Sep 2020 00:43:23
	System	20 Sep 2020 00:43:23

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-19T20:43:09', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '3e21a2ed-13c7-4213-88fe-4992027bcd5f' User entered 'None (0)'	System	20 Sep 2020 00:43:23
	System	20 Sep 2020 00:43:23

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-19T20:43:12', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '3e21a2ed-13c7-4213-88fe-4992027bcd5f' User entered 'None (0)'	System	20 Sep 2020 00:43:23
	System	20 Sep 2020 00:43:23

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

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)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-19T20:43:17', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '3e21a2ed-13c7-4213-88fe-4992027bcd5f' User entered 'No (N)'	System	20 Sep 2020 00:43:23
	System	20 Sep 2020 00:43:23

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-19T20:43:21', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '3e21a2ed-13c7-4213-88fe-4992027bcd5f' User entered '19 Sep 2020 20:43'	System	20 Sep 2020 00:43:23
	System	20 Sep 2020 00:43:23

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 3'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-20T21:04:37', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '2e7ac290-79f0-4401-b334-35ac816a1689' User entered 'None (0)'	System	21 Sep 2020 01:05:02
	System	21 Sep 2020 01:05:02

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-20T21:04:40', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '2e7ac290-79f0-4401-b334-35ac816a1689' User entered 'None (0)'	System	21 Sep 2020 01:05:02
	System	21 Sep 2020 01:05:02

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-20T21:04:43', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '2e7ac290-79f0-4401-b334-35ac816a1689' User entered 'None (0)'	System	21 Sep 2020 01:05:02
	System	21 Sep 2020 01:05:02

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-20T21:04:46', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '2e7ac290-79f0-4401-b334-35ac816a1689' User entered 'None (0)'	System	21 Sep 2020 01:05:02
	System	21 Sep 2020 01:05:02

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-20T21:04:49', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '2e7ac290-79f0-4401-b334-35ac816a1689' User entered 'None (0)'	System	21 Sep 2020 01:05:02
	System	21 Sep 2020 01:05:02

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-20T21:04:52', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '2e7ac290-79f0-4401-b334-35ac816a1689' User entered 'None (0)'	System	21 Sep 2020 01:05:02
	System	21 Sep 2020 01:05:02

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

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)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-20T21:04:56', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '2e7ac290-79f0-4401-b334-35ac816a1689' User entered 'No (N)'	System	21 Sep 2020 01:05:02
	System	21 Sep 2020 01:05:02

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-20T21:05:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '2e7ac290-79f0-4401-b334-35ac816a1689'	System	21 Sep 2020 01:05:02
User entered '20 Sep 2020 21:05'	System	21 Sep 2020 01:05:02

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 4'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-21T20:33:22', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f5577a12-02d3-4827-a528-b2fbb844bcd1' User entered 'None (0)'	System	22 Sep 2020 00:33:47
	System	22 Sep 2020 00:33:47

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-21T20:33:25', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f5577a12-02d3-4827-a528-b2fbb844bcd1' User entered 'None (0)'	System	22 Sep 2020 00:33:47
	System	22 Sep 2020 00:33:47

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-21T20:33:27', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f5577a12-02d3-4827-a528-b2fbb844bcd1' User entered 'None (0)'	System	22 Sep 2020 00:33:47
	System	22 Sep 2020 00:33:47

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-21T20:33:30', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f5577a12-02d3-4827-a528-b2fbb844bcd1' User entered 'None (0)'	System	22 Sep 2020 00:33:47
	System	22 Sep 2020 00:33:47

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-21T20:33:32', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f5577a12-02d3-4827-a528-b2fbb844bcd1' User entered 'None (0)'	System	22 Sep 2020 00:33:47
	System	22 Sep 2020 00:33:47

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-21T20:33:35', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f5577a12-02d3-4827-a528-b2fbb844bcd1' User entered 'None (0)'	System	22 Sep 2020 00:33:47
	System	22 Sep 2020 00:33:47

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

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)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-21T20:33:40', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f5577a12-02d3-4827-a528-b2fbb844bcd1' User entered 'No (N)'	System	22 Sep 2020 00:33:47
	System	22 Sep 2020 00:33:47

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-21T20:33:43', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f5577a12-02d3-4827-a528-b2fbb844bcd1' User entered '21 Sep 2020 20:33'	System	22 Sep 2020 00:33:47
	System	22 Sep 2020 00:33:47

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 5'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-22T18:59:40', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'aa8d1fa0-958d-4612-a102-f8c9e9f1e85a' User entered 'None (0)'	System	22 Sep 2020 23:00:10
	System	22 Sep 2020 23:00:10

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-22T18:59:43', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'aa8d1fa0-958d-4612-a102-f8c9e9f1e85a' User entered 'None (0)'	System	22 Sep 2020 23:00:10
	System	22 Sep 2020 23:00:10

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-22T18:59:46', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'aa8d1fa0-958d-4612-a102-f8c9e9f1e85a' User entered 'None (0)'	System	22 Sep 2020 23:00:10
	System	22 Sep 2020 23:00:10

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-22T18:59:50', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'aa8d1fa0-958d-4612-a102-f8c9e9f1e85a' User entered 'None (0)'	System	22 Sep 2020 23:00:10
	System	22 Sep 2020 23:00:10

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-22T18:59:52', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'aa8d1fa0-958d-4612-a102-f8c9e9f1e85a' User entered 'None (0)'	System	22 Sep 2020 23:00:10
	System	22 Sep 2020 23:00:10

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-22T18:59:55', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'aa8d1fa0-958d-4612-a102-f8c9e9f1e85a' User entered 'None (0)'	System	22 Sep 2020 23:00:10
	System	22 Sep 2020 23:00:10

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

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)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-22T19:00:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'aa8d1fa0-958d-4612-a102-f8c9e9f1e85a' User entered 'No (N)'	System	22 Sep 2020 23:00:10
	System	22 Sep 2020 23:00:10

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-22T19:00:05', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'aa8d1fa0-958d-4612-a102-f8c9e9f1e85a' User entered '22 Sep 2020 19:00'	System	22 Sep 2020 23:00:10
	System	22 Sep 2020 23:00:10

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 6'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-23T20:39:55', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '072e8068-e6bd-46f3-9a8c-02c0d2d75b5e' User entered 'None (0)'	System	24 Sep 2020 00:40:15
	System	24 Sep 2020 00:40:15

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-23T20:39:57', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '072e8068-e6bd-46f3-9a8c-02c0d2d75b5e' User entered 'None (0)'	System	24 Sep 2020 00:40:15
	System	24 Sep 2020 00:40:15

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-23T20:39:59', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '072e8068-e6bd-46f3-9a8c-02c0d2d75b5e' User entered 'None (0)'	System	24 Sep 2020 00:40:15
	System	24 Sep 2020 00:40:15

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-23T20:40:02', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '072e8068-e6bd-46f3-9a8c-02c0d2d75b5e' User entered 'None (0)'	System	24 Sep 2020 00:40:15
	System	24 Sep 2020 00:40:15

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-23T20:40:04', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '072e8068-e6bd-46f3-9a8c-02c0d2d75b5e' User entered 'None (0)'	System	24 Sep 2020 00:40:15
	System	24 Sep 2020 00:40:15

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-23T20:40:07', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '072e8068-e6bd-46f3-9a8c-02c0d2d75b5e' User entered 'None (0)'	System	24 Sep 2020 00:40:15
	System	24 Sep 2020 00:40:15

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

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)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-23T20:40:11', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '072e8068-e6bd-46f3-9a8c-02c0d2d75b5e' User entered 'No (N)'	System	24 Sep 2020 00:40:15
	System	24 Sep 2020 00:40:15

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-23T20:40:13', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '072e8068-e6bd-46f3-9a8c-02c0d2d75b5e' User entered '23 Sep 2020 20:40'	System	24 Sep 2020 00:40:15
	System	24 Sep 2020 00:40:15

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 7'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-24T14:15:25', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f16b5e76-3456-4523-8a74-b9cc58944747' User entered 'None (0)'	System	24 Sep 2020 18:15:53
	System	24 Sep 2020 18:15:53

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-24T14:15:27', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f16b5e76-3456-4523-8a74-b9cc58944747' User entered 'None (0)'	System	24 Sep 2020 18:15:53
	System	24 Sep 2020 18:15:53

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-24T14:15:30', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f16b5e76-3456-4523-8a74-b9cc58944747' User entered 'None (0)'	System	24 Sep 2020 18:15:53
	System	24 Sep 2020 18:15:53

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-24T14:15:32', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f16b5e76-3456-4523-8a74-b9cc58944747' User entered 'None (0)'	System	24 Sep 2020 18:15:53
	System	24 Sep 2020 18:15:53

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-24T14:15:41', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f16b5e76-3456-4523-8a74-b9cc58944747' User entered 'None (0)'	System	24 Sep 2020 18:15:53
	System	24 Sep 2020 18:15:53

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-24T14:15:43', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f16b5e76-3456-4523-8a74-b9cc58944747' User entered 'None (0)'	System	24 Sep 2020 18:15:53
	System	24 Sep 2020 18:15:53

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

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)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-24T14:15:46', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f16b5e76-3456-4523-8a74-b9cc58944747' User entered 'No (N)'	System	24 Sep 2020 18:15:53
	System	24 Sep 2020 18:15:53

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-09-24T14:15:50', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f16b5e76-3456-4523-8a74-b9cc58944747' User entered '24 Sep 2020 14:15'	System	24 Sep 2020 18:15:53
	System	24 Sep 2020 18:15:53

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:49:58

US3712064

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:21:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 13:19:50

US3712064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:21:26
User entered '25 Sep 2020'	(b) (4), (b) (6)	05 Oct 2020 13:19:50

US3712064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:21:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 13:19:50

US3712064

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:21:26
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 13:19:50

US3712064

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 17:21:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 13:20:35

US3712064

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered 'I'	System	05 Oct 2020 13:20:35

US3712064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:00:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 13:50:37

US3712064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:00:15
User entered '02 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 13:50:37

US3712064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:00:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Oct 2020 13:50:37

US3712064

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:00:15
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 13:50:37

US3712064

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:00:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 13:50:50

US3712064

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:27:00
User entered 'I'	System	12 Oct 2020 13:50:50

US3712064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:08
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:01:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 20:42:50

US3712064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:08
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:01:06
User entered '09 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 20:42:50

US3712064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:08
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:01:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Oct 2020 20:42:50

US3712064

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:08
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:01:06
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:42:50

US3712064

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:08
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:01:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 15:31:45

US3712064

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:08
User entered 'I'	System	16 Oct 2020 15:31:45

US3712064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:09:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 15:31:55

US3712064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:09:08
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 15:31:55

US3712064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:09:08
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Oct 2020 15:31:55

US3712064

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered 'VISIT2'	System	16 Oct 2020 15:31:55

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:13:00
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:13:00
User entered '10:10'	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered '16 Oct 2020 10:10'	System	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:13:00
User entered '36.8' C	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:00
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:00
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:00
User entered '76'	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered 'bpm'	System	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:00
User entered '16'	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered 'breaths/min'	System	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:43:23
User closed query 'Please confirm as source seems to note 140. If confirmed, please update or clarify otherwise.' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 18:43:19
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
Query 'Please confirm as source seems to note 140. If confirmed, please update or clarify otherwise.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 18:55:03
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 18:54:56
User entered '140' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 18:54:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:13:00
User opened query 'Please confirm as source seems to note 140. If confirmed, please update or clarify otherwise.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 22:11:46
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 17:45:18
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Oct 2020 17:45:18
User entered '131' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 17:45:18
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 20:41:16
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered 'mmHg'	System	19 Oct 2020 17:45:18
User entered empty.	System	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:43:25
User closed query 'Please confirm as source seems to note 86. If confirmed please update or clarify otherwise.' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 18:43:21
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
Query 'Please confirm as source seems to note 86. If confirmed please update or clarify otherwise.' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 18:55:08
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 18:54:56
User entered '86' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 18:54:56
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:13:00
User opened query 'Please confirm as source seems to note 86. If confirmed please update or clarify otherwise.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 22:12:10
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 17:45:18
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Oct 2020 17:45:18
User entered '76' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 17:45:18
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 20:41:16
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered 'mmHg'	System	19 Oct 2020 17:45:18
User entered empty.	System	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:13:00
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:00
User entered '12:03'	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered '16 Oct 2020 12:03'	System	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:13:00
User entered '37.1' C	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:00
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:00
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:00
User entered '76'	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered 'bpm'	System	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:00
User entered '16'	Tiffany (b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered 'breaths/min'	System	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:00
User entered '131'	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered 'mmHg'	System	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:00
User entered '76'	(b) (4), (b) (6)	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered 'mmHg'	System	16 Oct 2020 20:41:16

US3712064

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:06
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 15:32:28

US3712064

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:13:06
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 15:32:28

US3712064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 15:33:08

US3712064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:36
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 15:33:08

US3712064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

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 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:36
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 15:33:08

US3712064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User entered 'MRNA-1273 OR PLACEBO'	System	16 Oct 2020 15:33:08

US3712064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:36
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 15:33:08

US3712064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:36
User entered '11:28'	(b) (4), (b) (6)	16 Oct 2020 15:33:08

US3712064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User entered '16 Oct 2020 11:28'	System	16 Oct 2020 15:33:08

US3712064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:13:36
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	16 Oct 2020 15:33:08

US3712064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:13:36
User entered 'ONCE'	System	16 Oct 2020 15:33:08

US3712064

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:11

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User entered 'INTRAMUSCULAR'	System	16 Oct 2020 15:33:08

US3712064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:14:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 15:32:40

US3712064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:14:17
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 15:32:40

US3712064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:14:17
User entered '10:34'	(b) (4), (b) (6)	16 Oct 2020 15:32:40

US3712064

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User entered '16 Oct 2020 10:34'	System	16 Oct 2020 15:32:40

US3712064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:14:23
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 15:32:50

US3712064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Oct 2020 15:32:50

US3712064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:14:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 15:32:50

US3712064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:11

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:14:23
User entered '10:37'	(b) (4), (b) (6)	16 Oct 2020 15:32:50

US3712064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User entered '16 Oct 2020 10:37'	System	16 Oct 2020 15:32:50

US3712064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Oct 2020 15:32:50

US3712064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:37:26
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:10:35
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 20:32:42
Signature has been broken.	(b) (4), (b) (6)	15 Feb 2021 20:32:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 20:32:42
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:14:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 15:32:50

US3712064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:37:26
User signature succeeded.	William Smith (b) (4)	20 Feb 2021 17:10:35
DataPoint Un-verified.	(b) (4), (b) (6)	15 Feb 2021 20:32:42
Signature has been broken.	(b) (4), (b) (6)	15 Feb 2021 20:32:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 20:32:42
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:14:23
User entered '10:37'	(b) (4), (b) (6)	16 Oct 2020 15:32:50

US3712064

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User entered empty.	System	15 Feb 2021 20:32:42
User entered '16 Oct 2020 10:37'	System	16 Oct 2020 15:32:50

US3712064

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:15:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 15:32:53

US3712064

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User entered 'I'	System	16 Oct 2020 15:32:53

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T12:11:15', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'b6528cf5-3189-4529-9696-50517b389d9a' User entered 'Yes (Y)'	System	16 Oct 2020 16:11:32
	System	16 Oct 2020 16:11:32

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T12:11:21', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'b6528cf5-3189-4529-9696-50517b389d9a' User entered '98.9'	System	16 Oct 2020 16:11:32
	System	16 Oct 2020 16:11:32

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T12:11:25', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'b6528cf5-3189-4529-9696-50517b389d9a'	System	16 Oct 2020 16:11:32
User entered 'No (N)'	System	16 Oct 2020 16:11:32

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T12:11:29', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'b6528cf5-3189-4529-9696-50517b389d9a' User entered '16 Oct 2020 12:11'	System	16 Oct 2020 16:11:32
	System	16 Oct 2020 16:11:32

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '16 Oct 2020 11:48'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '16 Oct 2020 14:18'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T20:24:18', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '603ba89a-a703-483a-8e58-3d9d951abd3b' User entered 'Yes (Y)'	System	17 Oct 2020 00:25:43
	System	17 Oct 2020 00:25:43

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T20:25:30', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '603ba89a-a703-483a-8e58-3d9d951abd3b' User entered '98.6'	System	17 Oct 2020 00:25:43
	System	17 Oct 2020 00:25:43

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T20:25:34', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '603ba89a-a703-483a-8e58-3d9d951abd3b' User entered 'No (N)'	System	17 Oct 2020 00:25:43
	System	17 Oct 2020 00:25:43

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T20:25:39', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '603ba89a-a703-483a-8e58-3d9d951abd3b' User entered '16 Oct 2020 20:25'	System	17 Oct 2020 00:25:43
	System	17 Oct 2020 00:25:43

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '16 Oct 2020 15:13'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 2'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-17T19:36:05', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'ba0e0ee6-8828-46e8-8e90-cd55ea7c1638' User entered 'Yes (Y)'	System	17 Oct 2020 23:36:41
	System	17 Oct 2020 23:36:41

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-17T19:36:10', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'ba0e0ee6-8828-46e8-8e90-cd55ea7c1638' User entered '99.7'	System	17 Oct 2020 23:36:41
	System	17 Oct 2020 23:36:41

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-17T19:36:32', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'ba0e0ee6-8828-46e8-8e90-cd55ea7c1638'	System	17 Oct 2020 23:36:41
User entered 'No (N)'	System	17 Oct 2020 23:36:41

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-17T19:36:38', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'ba0e0ee6-8828-46e8-8e90-cd55ea7c1638' User entered '17 Oct 2020 19:36'	System	17 Oct 2020 23:36:41
	System	17 Oct 2020 23:36:41

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 3'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-18T18:43:20', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'e3989366-f5bd-4818-a4e7-e84098971e2f' User entered 'Yes (Y)'	System	18 Oct 2020 22:43:37
	System	18 Oct 2020 22:43:37

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-18T18:43:29', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'e3989366-f5bd-4818-a4e7-e84098971e2f' User entered '96.8'	System	18 Oct 2020 22:43:37
	System	18 Oct 2020 22:43:37

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-18T18:43:33', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'e3989366-f5bd-4818-a4e7-e84098971e2f' User entered 'No (N)'	System	18 Oct 2020 22:43:37
	System	18 Oct 2020 22:43:37

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-18T18:43:36', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'e3989366-f5bd-4818-a4e7-e84098971e2f' User entered '18 Oct 2020 18:43'	System	18 Oct 2020 22:43:37
	System	18 Oct 2020 22:43:37

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 4'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-19T19:06:11', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5e0ec72c-35a0-4643-827f-c6f65f22c9b7' User entered 'Yes (Y)'	System	19 Oct 2020 23:08:21
	System	19 Oct 2020 23:08:21

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-19T19:08:11', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5e0ec72c-35a0-4643-827f-c6f65f22c9b7' User entered '97.9'	System	19 Oct 2020 23:08:21
	System	19 Oct 2020 23:08:21

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-19T19:08:14', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5e0ec72c-35a0-4643-827f-c6f65f22c9b7' User entered 'No (N)'	System	19 Oct 2020 23:08:21
	System	19 Oct 2020 23:08:21

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-19T19:08:18', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5e0ec72c-35a0-4643-827f-c6f65f22c9b7' User entered '19 Oct 2020 19:08'	System	19 Oct 2020 23:08:21
	System	19 Oct 2020 23:08:21

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 5'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-20T16:26:39', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f68f2417-c3a8-4b93-ac66-353ef1d8fadb' User entered 'Yes (Y)'	System	20 Oct 2020 20:28:20
	System	20 Oct 2020 20:28:20

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-20T16:28:11', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f68f2417-c3a8-4b93-ac66-353ef1d8fadb' User entered '97.3'	System	20 Oct 2020 20:28:20
	System	20 Oct 2020 20:28:20

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-20T16:28:14', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f68f2417-c3a8-4b93-ac66-353ef1d8fadb' User entered 'No (N)'	System	20 Oct 2020 20:28:20
	System	20 Oct 2020 20:28:20

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-20T16:28:17', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f68f2417-c3a8-4b93-ac66-353ef1d8fadb' User entered '20 Oct 2020 16:28'	System	20 Oct 2020 20:28:20
	System	20 Oct 2020 20:28:20

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 6'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-21T16:47:48', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '65ff5a45-0d20-4798-8fda-bee15b5e0872' User entered 'Yes (Y)'	System	21 Oct 2020 20:48:13
	System	21 Oct 2020 20:48:13

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-21T16:47:54', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '65ff5a45-0d20-4798-8fda-bee15b5e0872'	System	21 Oct 2020 20:48:13
User entered '98.1'	System	21 Oct 2020 20:48:13

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-21T16:47:58', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '65ff5a45-0d20-4798-8fda-bee15b5e0872'	System	21 Oct 2020 20:48:13
User entered 'No (N)'	System	21 Oct 2020 20:48:13

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-21T16:48:10', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '65ff5a45-0d20-4798-8fda-bee15b5e0872'	System	21 Oct 2020 20:48:13
User entered '21 Oct 2020 16:48'	System	21 Oct 2020 20:48:13

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 7'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-22T21:55:42', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f3a19ebd-9955-4666-aa05-9cce479ba208' User entered 'Yes (Y)'	System	23 Oct 2020 01:57:35
	System	23 Oct 2020 01:57:35

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-22T21:57:24', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f3a19ebd-9955-4666-aa05-9cce479ba208' User entered '97.8'	System	23 Oct 2020 01:57:35
	System	23 Oct 2020 01:57:35

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-22T21:57:27', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f3a19ebd-9955-4666-aa05-9cce479ba208'	System	23 Oct 2020 01:57:35
User entered 'No (N)'	System	23 Oct 2020 01:57:35

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-22T21:57:32', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f3a19ebd-9955-4666-aa05-9cce479ba208' User entered '22 Oct 2020 21:57'	System	23 Oct 2020 01:57:35
	System	23 Oct 2020 01:57:35

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T12:11:34', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'b13a0ded-cdfc-493c-8569-eaa1a4fee72f' User entered 'None (1)'	System	16 Oct 2020 16:11:54
	System	16 Oct 2020 16:11:54

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T12:11:37', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'b13a0ded-cdfc-493c-8569-eaa1a4fee72f' User entered 'No (N)'	System	16 Oct 2020 16:11:54
	System	16 Oct 2020 16:11:54

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T12:11:40', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'b13a0ded-cdfc-493c-8569-eaa1a4fee72f' User entered 'No (N)'	System	16 Oct 2020 16:11:54
	System	16 Oct 2020 16:11:54

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T12:11:48', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'b13a0ded-cdfc-493c-8569-eaa1a4fee72f' User entered 'None (1)'	System	16 Oct 2020 16:11:54
	System	16 Oct 2020 16:11:54

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T12:11:51', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'b13a0ded-cdfc-493c-8569-eaa1a4fee72f' User entered '16 Oct 2020 12:11'	System	16 Oct 2020 16:11:54
	System	16 Oct 2020 16:11:54

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '16 Oct 2020 11:48'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '16 Oct 2020 14:18'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T20:25:44', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'd00f6440-092a-484b-8a22-c1991b379a67'	System	17 Oct 2020 00:26:10
User entered 'None (1)'	System	17 Oct 2020 00:26:10

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T20:25:48', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'd00f6440-092a-484b-8a22-c1991b379a67' User entered 'No (N)'	System	17 Oct 2020 00:26:10
	System	17 Oct 2020 00:26:10

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T20:25:51', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'd00f6440-092a-484b-8a22-c1991b379a67' User entered 'No (N)'	System	17 Oct 2020 00:26:10
	System	17 Oct 2020 00:26:10

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T20:26:02', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'd00f6440-092a-484b-8a22-c1991b379a67'	System	17 Oct 2020 00:26:10
User entered 'None (1)'	System	17 Oct 2020 00:26:10

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T20:26:05', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'd00f6440-092a-484b-8a22-c1991b379a67' User entered '16 Oct 2020 20:26'	System	17 Oct 2020 00:26:10
	System	17 Oct 2020 00:26:10

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '16 Oct 2020 15:13'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 2'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-17T19:36:47', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '05f4b9fa-2ca0-48e2-95c4-0801287248ef' User entered 'Does not interfere with activity (2)'	System	17 Oct 2020 23:38:52
	System	17 Oct 2020 23:38:52

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-17T19:36:54', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '05f4b9fa-2ca0-48e2-95c4-0801287248ef' User entered 'Yes (Y)'	System	17 Oct 2020 23:38:52
	System	17 Oct 2020 23:38:52

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-17T19:38:34', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '05f4b9fa-2ca0-48e2-95c4-0801287248ef' User entered '550'	System	17 Oct 2020 23:38:52
	System	17 Oct 2020 23:38:52

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-17T19:38:39', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '05f4b9fa-2ca0-48e2-95c4-0801287248ef' User entered 'No (N)'	System	17 Oct 2020 23:38:52
	System	17 Oct 2020 23:38:52

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-17T19:38:42', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '05f4b9fa-2ca0-48e2-95c4-0801287248ef' User entered 'None (1)'	System	17 Oct 2020 23:38:52
	System	17 Oct 2020 23:38:52

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-17T19:38:48', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '05f4b9fa-2ca0-48e2-95c4-0801287248ef' User entered '17 Oct 2020 19:38'	System	17 Oct 2020 23:38:52
	System	17 Oct 2020 23:38:52

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 3'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-18T18:43:47', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'b48fcef7-3691-4cbb-b3e2-e1b5721892d6' User entered 'None (1)'	System	18 Oct 2020 22:44:10
	System	18 Oct 2020 22:44:10

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-18T18:43:50', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'b48fcef7-3691-4cbb-b3e2-e1b5721892d6'	System	18 Oct 2020 22:44:10
User entered 'Yes (Y)'	System	18 Oct 2020 22:44:10

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-18T18:43:55', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'b48fcef7-3691-4cbb-b3e2-e1b5721892d6' User entered '80'	System	18 Oct 2020 22:44:10
	System	18 Oct 2020 22:44:10

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-18T18:44:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'b48fcef7-3691-4cbb-b3e2-e1b5721892d6' User entered 'No (N)'	System	18 Oct 2020 22:44:10
	System	18 Oct 2020 22:44:10

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-18T18:44:04', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'b48fcef7-3691-4cbb-b3e2-e1b5721892d6' User entered 'None (1)'	System	18 Oct 2020 22:44:10
	System	18 Oct 2020 22:44:10

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-18T18:44:07', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'b48fcef7-3691-4cbb-b3e2-e1b5721892d6' User entered '18 Oct 2020 18:44'	System	18 Oct 2020 22:44:10
	System	18 Oct 2020 22:44:10

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 4'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-19T19:08:23', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '0e984f3f-508a-41c7-8192-021c2ebda324'	System	19 Oct 2020 23:08:50
User entered 'None (1)'	System	19 Oct 2020 23:08:50

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-19T19:08:26', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '0e984f3f-508a-41c7-8192-021c2ebda324'	System	19 Oct 2020 23:08:50
User entered 'Yes (Y)'	System	19 Oct 2020 23:08:50

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-19T19:08:39', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '0e984f3f-508a-41c7-8192-021c2ebda324' User entered '80'	System	19 Oct 2020 23:08:50
	System	19 Oct 2020 23:08:50

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-19T19:08:44', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '0e984f3f-508a-41c7-8192-021c2ebda324'	System	19 Oct 2020 23:08:50
User entered 'No (N)'	System	19 Oct 2020 23:08:50

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-19T19:08:46', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '0e984f3f-508a-41c7-8192-021c2ebda324'	System	19 Oct 2020 23:08:50
User entered 'None (1)'	System	19 Oct 2020 23:08:50

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-19T19:08:49', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '0e984f3f-508a-41c7-8192-021c2ebda324' User entered '19 Oct 2020 19:08'	System	19 Oct 2020 23:08:50
	System	19 Oct 2020 23:08:50

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 5'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-20T16:28:22', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f2fc7eb6-1f81-48de-aff0-ae738d93e840'	System	20 Oct 2020 20:28:39
User entered 'None (1)'	System	20 Oct 2020 20:28:39

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-20T16:28:24', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f2fc7eb6-1f81-48de-aff0-ae738d93e840'	System	20 Oct 2020 20:28:39
User entered 'No (N)'	System	20 Oct 2020 20:28:39

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-20T16:28:27', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f2fc7eb6-1f81-48de-aff0-ae738d93e840'	System	20 Oct 2020 20:28:39
User entered 'No (N)'	System	20 Oct 2020 20:28:39

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-20T16:28:30', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f2fc7eb6-1f81-48de-aff0-ae738d93e840'	System	20 Oct 2020 20:28:39
User entered 'None (1)'	System	20 Oct 2020 20:28:39

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-20T16:28:33', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'f2fc7eb6-1f81-48de-aff0-ae738d93e840' User entered '20 Oct 2020 16:28'	System	20 Oct 2020 20:28:39
	System	20 Oct 2020 20:28:39

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 6'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-21T16:48:15', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'bdf649a-1c9c-4117-bcb9-418754f34ce3'	System	21 Oct 2020 20:48:28
User entered 'None (1)'	System	21 Oct 2020 20:48:28

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-21T16:48:18', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'bdff649a-1c9c-4117-bcb9-418754f34ce3'	System	21 Oct 2020 20:48:28
User entered 'No (N)'	System	21 Oct 2020 20:48:28

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-21T16:48:20', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'bdff649a-1c9c-4117-bcb9-418754f34ce3'	System	21 Oct 2020 20:48:28
User entered 'No (N)'	System	21 Oct 2020 20:48:28

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-21T16:48:23', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'bdf649a-1c9c-4117-bcb9-418754f34ce3'	System	21 Oct 2020 20:48:28
User entered 'None (1)'	System	21 Oct 2020 20:48:28

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-21T16:48:26', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'bdff649a-1c9c-4117-bcb9-418754f34ce3' User entered '21 Oct 2020 16:48'	System	21 Oct 2020 20:48:28
	System	21 Oct 2020 20:48:28

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 7'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-22T21:57:36', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '9499e3cf-493a-49c7-b387-ace58cc2a4f1' User entered 'None (1)'	System	23 Oct 2020 01:57:51
	System	23 Oct 2020 01:57:51

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-22T21:57:39', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '9499e3cf-493a-49c7-b387-ace58cc2a4f1' User entered 'No (N)'	System	23 Oct 2020 01:57:51
	System	23 Oct 2020 01:57:51

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-22T21:57:42', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '9499e3cf-493a-49c7-b387-ace58cc2a4f1' User entered 'No (N)'	System	23 Oct 2020 01:57:51
	System	23 Oct 2020 01:57:51

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-22T21:57:45', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '9499e3cf-493a-49c7-b387-ace58cc2a4f1' User entered 'None (1)'	System	23 Oct 2020 01:57:51
	System	23 Oct 2020 01:57:51

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-22T21:57:49', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '9499e3cf-493a-49c7-b387-ace58cc2a4f1' User entered '22 Oct 2020 21:57'	System	23 Oct 2020 01:57:51
	System	23 Oct 2020 01:57:51

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T12:11:57', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '6bdaef14-a81f-45b3-a6be-619783cf10cc' User entered 'None (0)'	System	16 Oct 2020 16:12:24
	System	16 Oct 2020 16:12:24

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T12:12:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '6bdaef14-a81f-45b3-a6be-619783cf10cc' User entered 'None (0)'	System	16 Oct 2020 16:12:24
	System	16 Oct 2020 16:12:24

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T12:12:02', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '6bdaef14-a81f-45b3-a6be-619783cf10cc' User entered 'None (0)'	System	16 Oct 2020 16:12:24
	System	16 Oct 2020 16:12:24

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T12:12:05', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '6bdaef14-a81f-45b3-a6be-619783cf10cc' User entered 'None (0)'	System	16 Oct 2020 16:12:24
	System	16 Oct 2020 16:12:24

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T12:12:08', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '6bdaef14-a81f-45b3-a6be-619783cf10cc' User entered 'None (0)'	System	16 Oct 2020 16:12:24
	System	16 Oct 2020 16:12:24

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T12:12:11', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '6bdaef14-a81f-45b3-a6be-619783cf10cc' User entered 'None (0)'	System	16 Oct 2020 16:12:24
	System	16 Oct 2020 16:12:24

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

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)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T12:12:17', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '6bdaef14-a81f-45b3-a6be-619783cf10cc'	System	16 Oct 2020 16:12:24
User entered 'No (N)'	System	16 Oct 2020 16:12:24

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T12:12:22', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '6bdaef14-a81f-45b3-a6be-619783cf10cc' User entered '16 Oct 2020 12:12'	System	16 Oct 2020 16:12:24
	System	16 Oct 2020 16:12:24

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '16 Oct 2020 11:48'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '16 Oct 2020 14:18'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T20:26:10', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '25f8acd0-321b-41ee-86bf-4424fb266191' User entered 'None (0)'	System	17 Oct 2020 00:26:31
	System	17 Oct 2020 00:26:31

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T20:26:12', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '25f8acd0-321b-41ee-86bf-4424fb266191' User entered 'None (0)'	System	17 Oct 2020 00:26:31
	System	17 Oct 2020 00:26:31

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T20:26:14', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '25f8acd0-321b-41ee-86bf-4424fb266191' User entered 'None (0)'	System	17 Oct 2020 00:26:31
	System	17 Oct 2020 00:26:31

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T20:26:17', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '25f8acd0-321b-41ee-86bf-4424fb266191' User entered 'None (0)'	System	17 Oct 2020 00:26:31
	System	17 Oct 2020 00:26:31

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T20:26:20', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '25f8acd0-321b-41ee-86bf-4424fb266191' User entered 'None (0)'	System	17 Oct 2020 00:26:31
	System	17 Oct 2020 00:26:31

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T20:26:22', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '25f8acd0-321b-41ee-86bf-4424fb266191' User entered 'None (0)'	System	17 Oct 2020 00:26:31
	System	17 Oct 2020 00:26:31

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

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)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T20:26:25', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '25f8acd0-321b-41ee-86bf-4424fb266191' User entered 'No (N)'	System	17 Oct 2020 00:26:31
	System	17 Oct 2020 00:26:31

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-16T20:26:28', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '25f8acd0-321b-41ee-86bf-4424fb266191' User entered '16 Oct 2020 20:26'	System	17 Oct 2020 00:26:31
	System	17 Oct 2020 00:26:31

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '16 Oct 2020 15:13'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 2'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-17T19:38:52', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '56b29647-8733-4ad5-a25f-4d4270e3b7e7' User entered 'None (0)'	System	17 Oct 2020 23:39:21
	System	17 Oct 2020 23:39:21

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-17T19:38:55', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '56b29647-8733-4ad5-a25f-4d4270e3b7e7' User entered 'None (0)'	System	17 Oct 2020 23:39:21
	System	17 Oct 2020 23:39:21

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-17T19:38:57', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '56b29647-8733-4ad5-a25f-4d4270e3b7e7' User entered 'None (0)'	System	17 Oct 2020 23:39:21
	System	17 Oct 2020 23:39:21

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-17T19:38:59', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '56b29647-8733-4ad5-a25f-4d4270e3b7e7' User entered 'None (0)'	System	17 Oct 2020 23:39:21
	System	17 Oct 2020 23:39:21

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-17T19:39:02', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '56b29647-8733-4ad5-a25f-4d4270e3b7e7' User entered 'None (0)'	System	17 Oct 2020 23:39:21
	System	17 Oct 2020 23:39:21

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-17T19:39:05', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '56b29647-8733-4ad5-a25f-4d4270e3b7e7' User entered 'None (0)'	System	17 Oct 2020 23:39:21
	System	17 Oct 2020 23:39:21

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

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)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-17T19:39:08', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '56b29647-8733-4ad5-a25f-4d4270e3b7e7' User entered 'No (N)'	System	17 Oct 2020 23:39:21
	System	17 Oct 2020 23:39:21

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-17T19:39:12', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '56b29647-8733-4ad5-a25f-4d4270e3b7e7' User entered '17 Oct 2020 19:39'	System	17 Oct 2020 23:39:21
	System	17 Oct 2020 23:39:21

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 3'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-18T18:44:17', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '763336c8-284e-403f-a388-2c5dc6666d05' User entered 'None (0)'	System	18 Oct 2020 22:44:38
	System	18 Oct 2020 22:44:38

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-18T18:44:19', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '763336c8-284e-403f-a388-2c5dc6666d05' User entered 'None (0)'	System	18 Oct 2020 22:44:38
	System	18 Oct 2020 22:44:38

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-18T18:44:21', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '763336c8-284e-403f-a388-2c5dc6666d05' User entered 'None (0)'	System	18 Oct 2020 22:44:38
	System	18 Oct 2020 22:44:38

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-18T18:44:24', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '763336c8-284e-403f-a388-2c5dc6666d05' User entered 'None (0)'	System	18 Oct 2020 22:44:38
	System	18 Oct 2020 22:44:38

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-18T18:44:27', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '763336c8-284e-403f-a388-2c5dc6666d05' User entered 'None (0)'	System	18 Oct 2020 22:44:38
	System	18 Oct 2020 22:44:38

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-18T18:44:30', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '763336c8-284e-403f-a388-2c5dc6666d05' User entered 'None (0)'	System	18 Oct 2020 22:44:38
	System	18 Oct 2020 22:44:38

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

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)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-18T18:44:33', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '763336c8-284e-403f-a388-2c5dc6666d05' User entered 'No (N)'	System	18 Oct 2020 22:44:38
	System	18 Oct 2020 22:44:38

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-18T18:44:35', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '763336c8-284e-403f-a388-2c5dc6666d05' User entered '18 Oct 2020 18:44'	System	18 Oct 2020 22:44:38
	System	18 Oct 2020 22:44:38

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 4'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-19T19:08:52', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '67cce81b-b9ae-408f-ae52-62fdb2cbd37f' User entered 'None (0)'	System	19 Oct 2020 23:09:14
	System	19 Oct 2020 23:09:14

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-19T19:08:54', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '67cce81b-b9ae-408f-ae52-62fdb2cbd37f' User entered 'None (0)'	System	19 Oct 2020 23:09:14
	System	19 Oct 2020 23:09:14

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-19T19:08:57', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '67cce81b-b9ae-408f-ae52-62fdb2cbd37f' User entered 'None (0)'	System	19 Oct 2020 23:09:14
	System	19 Oct 2020 23:09:14

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-19T19:08:59', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '67cce81b-b9ae-408f-ae52-62fdb2cbd37f' User entered 'None (0)'	System	19 Oct 2020 23:09:14
	System	19 Oct 2020 23:09:14

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-19T19:09:02', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '67cce81b-b9ae-408f-ae52-62fdb2cbd37f' User entered 'None (0)'	System	19 Oct 2020 23:09:14
	System	19 Oct 2020 23:09:14

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-19T19:09:05', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '67cce81b-b9ae-408f-ae52-62fdb2cbd37f' User entered 'None (0)'	System	19 Oct 2020 23:09:14
	System	19 Oct 2020 23:09:14

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

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)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-19T19:09:09', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '67cce81b-b9ae-408f-ae52-62fdb2cbd37f' User entered 'No (N)'	System	19 Oct 2020 23:09:14
	System	19 Oct 2020 23:09:14

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-19T19:09:12', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '67cce81b-b9ae-408f-ae52-62fdb2cbd37f' User entered '19 Oct 2020 19:09'	System	19 Oct 2020 23:09:14
	System	19 Oct 2020 23:09:14

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 5'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-20T16:28:37', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5678185a-1476-4aaa-9502-89ad7f16f7f2' User entered 'None (0)'	System	20 Oct 2020 20:28:58
	System	20 Oct 2020 20:28:58

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-20T16:28:39', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5678185a-1476-4aaa-9502-89ad7f16f7f2' User entered 'None (0)'	System	20 Oct 2020 20:28:58
	System	20 Oct 2020 20:28:58

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-20T16:28:42', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5678185a-1476-4aaa-9502-89ad7f16f7f2' User entered 'None (0)'	System	20 Oct 2020 20:28:58
	System	20 Oct 2020 20:28:58

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-20T16:28:45', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5678185a-1476-4aaa-9502-89ad7f16f7f2' User entered 'None (0)'	System	20 Oct 2020 20:28:58
	System	20 Oct 2020 20:28:58

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-20T16:28:47', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5678185a-1476-4aaa-9502-89ad7f16f7f2' User entered 'None (0)'	System	20 Oct 2020 20:28:58
	System	20 Oct 2020 20:28:58

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-20T16:28:50', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5678185a-1476-4aaa-9502-89ad7f16f7f2' User entered 'None (0)'	System	20 Oct 2020 20:28:58
	System	20 Oct 2020 20:28:58

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

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)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-20T16:28:52', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5678185a-1476-4aaa-9502-89ad7f16f7f2'	System	20 Oct 2020 20:28:58
User entered 'No (N)'	System	20 Oct 2020 20:28:58

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-20T16:28:56', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5678185a-1476-4aaa-9502-89ad7f16f7f2' User entered '20 Oct 2020 16:28'	System	20 Oct 2020 20:28:58
	System	20 Oct 2020 20:28:58

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 6'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-21T16:48:30', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '893ddf32-0e08-4a8b-b59a-ea19a9b491e6' User entered 'None (0)'	System	21 Oct 2020 20:48:51
	System	21 Oct 2020 20:48:51

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-21T16:48:32', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '893ddf32-0e08-4a8b-b59a-ea19a9b491e6' User entered 'None (0)'	System	21 Oct 2020 20:48:51
	System	21 Oct 2020 20:48:51

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-21T16:48:34', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '893ddf32-0e08-4a8b-b59a-ea19a9b491e6' User entered 'None (0)'	System	21 Oct 2020 20:48:51
	System	21 Oct 2020 20:48:51

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-21T16:48:37', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '893ddf32-0e08-4a8b-b59a-ea19a9b491e6' User entered 'None (0)'	System	21 Oct 2020 20:48:51
	System	21 Oct 2020 20:48:51

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-21T16:48:39', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '893ddf32-0e08-4a8b-b59a-ea19a9b491e6' User entered 'None (0)'	System	21 Oct 2020 20:48:51
	System	21 Oct 2020 20:48:51

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-21T16:48:41', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '893ddf32-0e08-4a8b-b59a-ea19a9b491e6' User entered 'None (0)'	System	21 Oct 2020 20:48:51
	System	21 Oct 2020 20:48:51

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

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)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-21T16:48:44', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '893ddf32-0e08-4a8b-b59a-ea19a9b491e6' User entered 'No (N)'	System	21 Oct 2020 20:48:51
	System	21 Oct 2020 20:48:51

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-21T16:48:49', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '893ddf32-0e08-4a8b-b59a-ea19a9b491e6' User entered '21 Oct 2020 16:48'	System	21 Oct 2020 20:48:51
	System	21 Oct 2020 20:48:51

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	16 Oct 2020 15:33:08
User entered 'Day 7'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-22T21:57:53', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5df457ad-0269-45ae-b24a-66cbb513b1a0' User entered 'None (0)'	System	23 Oct 2020 01:58:13
	System	23 Oct 2020 01:58:13

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-22T21:57:55', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5df457ad-0269-45ae-b24a-66cbb513b1a0' User entered 'None (0)'	System	23 Oct 2020 01:58:13
	System	23 Oct 2020 01:58:13

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-22T21:57:57', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5df457ad-0269-45ae-b24a-66cbb513b1a0' User entered 'None (0)'	System	23 Oct 2020 01:58:13
	System	23 Oct 2020 01:58:13

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-22T21:58:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5df457ad-0269-45ae-b24a-66cbb513b1a0' User entered 'None (0)'	System	23 Oct 2020 01:58:13
	System	23 Oct 2020 01:58:13

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-22T21:58:02', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5df457ad-0269-45ae-b24a-66cbb513b1a0' User entered 'None (0)'	System	23 Oct 2020 01:58:13
	System	23 Oct 2020 01:58:13

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-22T21:58:04', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5df457ad-0269-45ae-b24a-66cbb513b1a0' User entered 'None (0)'	System	23 Oct 2020 01:58:13
	System	23 Oct 2020 01:58:13

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

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)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-22T21:58:07', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5df457ad-0269-45ae-b24a-66cbb513b1a0' User entered 'No (N)'	System	23 Oct 2020 01:58:13
	System	23 Oct 2020 01:58:13

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-10-22T21:58:10', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '5df457ad-0269-45ae-b24a-66cbb513b1a0' User entered '22 Oct 2020 21:58'	System	23 Oct 2020 01:58:13
	System	23 Oct 2020 01:58:13

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 15:33:08

US3712064

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 15:33:08

US3712064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:19:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 12:20:20

US3712064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:19:17
User entered '23 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 12:20:20

US3712064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:19:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Oct 2020 12:20:20

US3712064

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:19:17
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 12:20:20

US3712064

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:37:35
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Oct 2020 12:21:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 12:21:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 12:21:13
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 12:21:11
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 12:21:11

US3712064

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User entered '1'	System	29 Oct 2020 12:21:13
User entered empty.	System	29 Oct 2020 12:21:11

US3712064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:49:38
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:05:26

US3712064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:49:38
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:05:26

US3712064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:49:38
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:05:26

US3712064

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:49:38
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:05:26

US3712064

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:50:13
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:50:51

US3712064

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User entered 'I'	System	09 Nov 2020 17:50:51

US3712064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:13:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 17:51:01

US3712064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:13:05
User entered '06 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 17:51:01

US3712064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:13:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Nov 2020 17:51:01

US3712064

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:13:05
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 17:51:01

US3712064

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:13:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 17:51:02

US3712064

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:21:59
User entered 'I'	System	09 Nov 2020 17:51:02

US3712064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 21:51:21

US3712064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:15
User entered '13 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 21:51:21

US3712064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:15
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Nov 2020 21:51:21

US3712064

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered 'VISIT3'	System	16 Nov 2020 21:51:21

US3712064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:16:22
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 21:51:23

US3712064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:16:22
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:51:23

US3712064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:16:22
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:51:23

US3712064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered empty.	System	16 Nov 2020 21:51:23

US3712064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:16:22
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:51:23

US3712064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:16:22
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:51:23

US3712064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:16:22
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:51:23

US3712064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:16:22
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:51:23

US3712064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered empty.	System	16 Nov 2020 21:51:23

US3712064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:16:22
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:51:23

US3712064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered empty.	System	16 Nov 2020 21:51:23

US3712064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:16:22
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:51:23

US3712064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered empty.	System	16 Nov 2020 21:51:23

US3712064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:16:22
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:51:23

US3712064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered empty.	System	16 Nov 2020 21:51:23

US3712064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24

US3712064

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24

US3712064

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:17:21
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 21:51:26

US3712064

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:17:21
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 21:51:26

US3712064

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:17:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 21:51:41

US3712064

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:17:37
User entered '13 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 21:51:41

US3712064

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:17:37
User entered '10:54'	(b) (4), (b) (6)	16 Nov 2020 21:51:41

US3712064

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered '13 Nov 2020 10:54'	System	16 Nov 2020 21:51:41

US3712064

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User signature succeeded.	William Smith (b) (4)	12 Feb 2021 23:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:17:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 21:51:43

US3712064

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:22:24
User entered 'I'	System	16 Nov 2020 21:51:43

US3712064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered 'Day 64'	System	18 Sep 2020 16:49:58

US3712064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-11-18T16:58:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '0c7cc685-3f2c-4113-b94f-190faa192e9f'	System	18 Nov 2020 21:58:12
User entered 'No (N)'	System	18 Nov 2020 21:58:12

US3712064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-11-18T16:58:04', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '0c7cc685-3f2c-4113-b94f-190faa192e9f'	System	18 Nov 2020 21:58:12
User entered 'No (N)'	System	18 Nov 2020 21:58:12

US3712064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-11-18T16:58:09', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '0c7cc685-3f2c-4113-b94f-190faa192e9f' User entered '18 Nov 2020 16:58:09'	System	18 Nov 2020 21:58:12
	System	18 Nov 2020 21:58:12

US3712064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered '18 Nov 2020 00:01'	System	18 Sep 2020 16:49:58

US3712064

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:08:37
Data entry locked.	System	18 Sep 2020 16:49:58
User entered '22 Nov 2020 23:59'	System	18 Sep 2020 16:49:58

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-11-24T04:50:44', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '92acfcbb-aef8-4af1-abc5-15a4e089a96e' User entered 'No (N)'	System	24 Nov 2020 09:50:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-11-24T04:50:49', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '92acfcbb-aef8-4af1-abc5-15a4e089a96e' User entered 'No (N)'	System	24 Nov 2020 09:50:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-11-24T04:50:56', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '92acfcbb-aef8-4af1-abc5-15a4e089a96e' User entered '24 Nov 2020 04:50:56'	System	24 Nov 2020 09:50:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-11-29T04:41:41', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '3e42da02-928c-4605-a31e-6ce5d086bcec' User entered 'No (N)'	System	29 Nov 2020 09:41:57

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-11-29T04:41:45', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '3e42da02-928c-4605-a31e-6ce5d086bcec' User entered 'No (N)'	System	29 Nov 2020 09:41:57

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-11-29T04:41:52', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '3e42da02-928c-4605-a31e-6ce5d086bcec' User entered '29 Nov 2020 04:41:52'	System	29 Nov 2020 09:41:57
	System	29 Nov 2020 09:41:57

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-12-06T01:28:12', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'd43f3b09-032c-4c26-85d1-b960a4ae4cb1' User entered 'No (N)'	System	06 Dec 2020 06:28:29
	System	06 Dec 2020 06:28:29

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-12-06T01:28:19', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'd43f3b09-032c-4c26-85d1-b960a4ae4cb1' User entered 'No (N)'	System	06 Dec 2020 06:28:29
	System	06 Dec 2020 06:28:29

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-12-06T01:28:25', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'd43f3b09-032c-4c26-85d1-b960a4ae4cb1' User entered '06 Dec 2020 01:28:25'	System	06 Dec 2020 06:28:29
	System	06 Dec 2020 06:28:29

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-12-15T11:23:48', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'ff5f0c86-9b76-4435-b34e-3956ad6ba74e'	System	15 Dec 2020 16:23:57
User entered 'No (N)'	System	15 Dec 2020 16:23:57

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-12-15T11:23:51', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'ff5f0c86-9b76-4435-b34e-3956ad6ba74e'	System	15 Dec 2020 16:23:57
User entered 'No (N)'	System	15 Dec 2020 16:23:57

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-12-15T11:23:55', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'ff5f0c86-9b76-4435-b34e-3956ad6ba74e' User entered '15 Dec 2020 11:23:55'	System	15 Dec 2020 16:23:57
	System	15 Dec 2020 16:23:57

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-12-20T00:01:42', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '1630e8ce-9bd0-4c11-8b7c-b69ff39c38f6' User entered 'No (N)'	System	20 Dec 2020 05:02:13
	System	20 Dec 2020 05:02:13

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-12-20T00:01:45', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '1630e8ce-9bd0-4c11-8b7c-b69ff39c38f6' User entered 'No (N)'	System	20 Dec 2020 05:02:13
	System	20 Dec 2020 05:02:13

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-12-20T00:01:48', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '1630e8ce-9bd0-4c11-8b7c-b69ff39c38f6' User entered '20 Dec 2020 00:01:48'	System	20 Dec 2020 05:02:13
	System	20 Dec 2020 05:02:13

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-12-29T12:00:55', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '119ca824-101e-4c98-af19-21e1bbe770f6'	System	29 Dec 2020 17:01:20
User entered 'Yes (Y)'	System	29 Dec 2020 17:01:20

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-12-29T12:00:59', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '119ca824-101e-4c98-af19-21e1bbe770f6'	System	29 Dec 2020 17:01:20
User entered 'No (N)'	System	29 Dec 2020 17:01:20

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-12-29T12:01:03', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '119ca824-101e-4c98-af19-21e1bbe770f6' User entered 'No (N)'	System	29 Dec 2020 17:01:20
	System	29 Dec 2020 17:01:20

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-12-29T12:01:10', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '119ca824-101e-4c98-af19-21e1bbe770f6'	System	29 Dec 2020 17:01:20
User entered 'No (N)'	System	29 Dec 2020 17:01:20

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2020-12-29T12:01:14', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '119ca824-101e-4c98-af19-21e1bbe770f6' User entered '29 Dec 2020 12:01:14'	System	29 Dec 2020 17:01:20
	System	29 Dec 2020 17:01:20

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-01-04T07:08:51', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '03ccd105-163a-4f64-8b4c-e868f8f5490b' User entered 'Yes (Y)'	System	04 Jan 2021 12:09:13
	System	04 Jan 2021 12:09:13

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-01-04T07:08:55', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '03ccd105-163a-4f64-8b4c-e868f8f5490b'	System	04 Jan 2021 12:09:13
User entered 'No (N)'	System	04 Jan 2021 12:09:13

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-01-04T07:09:02', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '03ccd105-163a-4f64-8b4c-e868f8f5490b' User entered 'No (N)'	System	04 Jan 2021 12:09:13

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-01-04T07:09:08', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '03ccd105-163a-4f64-8b4c-e868f8f5490b'	System	04 Jan 2021 12:09:13
User entered 'No (N)'	System	04 Jan 2021 12:09:13

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-01-04T07:09:12', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '03ccd105-163a-4f64-8b4c-e868f8f5490b' User entered '04 Jan 2021 07:09:12'	System	04 Jan 2021 12:09:13
	System	04 Jan 2021 12:09:13

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-01-10T09:08:21', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '25cb8354-67aa-4ebd-a99e-556802115231' User entered 'Yes (Y)'	System	10 Jan 2021 14:09:22

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-01-10T09:08:55', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '25cb8354-67aa-4ebd-a99e-556802115231' User entered 'No (N)'	System	10 Jan 2021 14:09:22

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-01-10T09:08:48', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '25cb8354-67aa-4ebd-a99e-556802115231' User entered 'No (N)'	System	10 Jan 2021 14:09:22

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-01-10T09:09:04', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '25cb8354-67aa-4ebd-a99e-556802115231' User entered 'Yes (Y)'	System	10 Jan 2021 14:09:22

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-01-10T09:09:08', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '25cb8354-67aa-4ebd-a99e-556802115231'	System	10 Jan 2021 14:09:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 14:09:22

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-01-10T09:09:13', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '25cb8354-67aa-4ebd-a99e-556802115231' User entered '10 Jan 2021 09:09:13'	System	10 Jan 2021 14:09:22

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-01-20T18:04:47', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '68713411-cc2c-4aea-a27e-14150d9fa722' User entered 'No (N)'	System	20 Jan 2021 23:05:01

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-01-20T18:04:51', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '68713411-cc2c-4aea-a27e-14150d9fa722' User entered 'No (N)'	System	20 Jan 2021 23:05:01

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-01-20T18:04:56', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '68713411-cc2c-4aea-a27e-14150d9fa722'	System	20 Jan 2021 23:05:01
User entered '20 Jan 2021 18:04:56'	System	20 Jan 2021 23:05:01

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-01-24T04:29:22', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '18634ce9-f6e2-45e4-8030-a891cb0699ec' User entered 'No (N)'	System	24 Jan 2021 09:29:43

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-01-24T04:29:36', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '18634ce9-f6e2-45e4-8030-a891cb0699ec' User entered 'No (N)'	System	24 Jan 2021 09:29:43

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-01-24T04:29:40', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '18634ce9-f6e2-45e4-8030-a891cb0699ec' User entered '24 Jan 2021 04:29:40'	System	24 Jan 2021 09:29:43
	System	24 Jan 2021 09:29:43

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-02-03T10:47:05', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '65aeb5d5-b097-42cb-af1b-2fbc67ca2d5e' User entered 'No (N)'	System	03 Feb 2021 15:47:15
	System	03 Feb 2021 15:47:15

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-02-03T10:47:08', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '65aeb5d5-b097-42cb-af1b-2fbc67ca2d5e' User entered 'No (N)'	System	03 Feb 2021 15:47:15

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-02-03T10:47:12', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '65aeb5d5-b097-42cb-af1b-2fbc67ca2d5e' User entered '03 Feb 2021 10:47:12'	System	03 Feb 2021 15:47:15
	System	03 Feb 2021 15:47:15

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-02-07T06:48:44', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '94328fd0-f267-46e1-85c5-ba9edca04155'	System	07 Feb 2021 11:48:55
User entered 'No (N)'	System	07 Feb 2021 11:48:55

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-02-07T06:48:48', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '94328fd0-f267-46e1-85c5-ba9edca04155'	System	07 Feb 2021 11:48:55
User entered 'No (N)'	System	07 Feb 2021 11:48:55

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-02-07T06:48:52', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '94328fd0-f267-46e1-85c5-ba9edca04155' User entered '07 Feb 2021 06:48:52'	System	07 Feb 2021 11:48:55
	System	07 Feb 2021 11:48:55

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-02-16T12:22:24', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '7155d300-ac73-4d51-89c6-9d6aca1b460e' User entered 'No (N)'	System	16 Feb 2021 17:25:27
	System	16 Feb 2021 17:25:27

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-02-16T12:22:42', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '7155d300-ac73-4d51-89c6-9d6aca1b460e' User entered 'Yes (Y)'	System	16 Feb 2021 17:25:27
	System	16 Feb 2021 17:25:27

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-02-16T12:22:49', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '7155d300-ac73-4d51-89c6-9d6aca1b460e'	System	16 Feb 2021 17:25:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Feb 2021 17:25:27

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-02-16T12:22:53', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '7155d300-ac73-4d51-89c6-9d6aca1b460e' User entered '16 Feb 2021 12:22:53'	System	16 Feb 2021 17:25:27
	System	16 Feb 2021 17:25:27

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-02-21T15:38:48', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'a5ab1c90-bfc6-47c8-a2ab-485f734294a7' User entered 'No (N)'	System	21 Feb 2021 20:39:05
	System	21 Feb 2021 20:39:05

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-02-21T15:38:55', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'a5ab1c90-bfc6-47c8-a2ab-485f734294a7' User entered 'No (N)'	System	21 Feb 2021 20:39:05

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-02-21T15:39:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'a5ab1c90-bfc6-47c8-a2ab-485f734294a7' User entered '21 Feb 2021 15:39:00'	System	21 Feb 2021 20:39:05
	System	21 Feb 2021 20:39:05

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-03-01T06:03:20-05:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '61d36274-f8e9-418d-9428-c12ca8acaa23'	System	07 Mar 2021 15:57:31
User entered 'No (N)'	System	07 Mar 2021 15:57:31

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-03-01T06:03:24-05:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '61d36274-f8e9-418d-9428-c12ca8acaa23'	System	07 Mar 2021 15:57:31
User entered 'No (N)'	System	07 Mar 2021 15:57:31

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-03-01T06:03:29-05:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '61d36274-f8e9-418d-9428-c12ca8acaa23'	System	07 Mar 2021 15:57:31
User entered '01 Mar 2021 06:03:29'	System	07 Mar 2021 15:57:31

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-03-07T10:57:35-05:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '8ee4323e-ace1-4f26-a017-f855542891a0'	System	07 Mar 2021 15:57:59
User entered 'No (N)'	System	07 Mar 2021 15:57:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-03-07T10:57:51-05:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '8ee4323e-ace1-4f26-a017-f855542891a0'	System	07 Mar 2021 15:57:59
User entered 'No (N)'	System	07 Mar 2021 15:57:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-03-07T10:57:54-05:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '8ee4323e-ace1-4f26-a017-f855542891a0' User entered '07 Mar 2021 10:57:54'	System	07 Mar 2021 15:57:59
	System	07 Mar 2021 15:57:59

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-03-14T05:41:19-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '87d6c821-0e88-4aee-ae2d-2ce60a00241e'	System	14 Mar 2021 09:41:30
User entered 'No (N)'	System	14 Mar 2021 09:41:30

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-03-14T05:41:22-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '87d6c821-0e88-4aee-ae2d-2ce60a00241e' User entered 'No (N)'	System	14 Mar 2021 09:41:30
	System	14 Mar 2021 09:41:30

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-03-14T05:41:26-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '87d6c821-0e88-4aee-ae2d-2ce60a00241e' User entered '14 Mar 2021 05:41:26'	System	14 Mar 2021 09:41:30
	System	14 Mar 2021 09:41:30

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-03-21T05:15:06-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '7084ce6a-2812-498e-bb64-5da90cdab6fa' User entered 'No (N)'	System	21 Mar 2021 09:15:17
	System	21 Mar 2021 09:15:17

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-03-21T05:15:09-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '7084ce6a-2812-498e-bb64-5da90cdab6fa' User entered 'No (N)'	System	21 Mar 2021 09:15:17
	System	21 Mar 2021 09:15:17

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-03-21T05:15:13-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '7084ce6a-2812-498e-bb64-5da90cdab6fa' User entered '21 Mar 2021 05:15:13'	System	21 Mar 2021 09:15:17
	System	21 Mar 2021 09:15:17

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-03-28T05:00:35-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'e1243548-8283-491b-82a9-527d74391d3f'	System	04 Apr 2021 13:02:55
User entered 'No (N)'	System	04 Apr 2021 13:02:55

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-03-28T05:00:39-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'e1243548-8283-491b-82a9-527d74391d3f'	System	04 Apr 2021 13:02:55
User entered 'No (N)'	System	04 Apr 2021 13:02:55

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-03-28T05:00:44-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'e1243548-8283-491b-82a9-527d74391d3f' User entered '28 Mar 2021 05:00:44'	System	04 Apr 2021 13:02:55

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-04-04T09:02:53-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '30d9eb9c-a003-4f83-9f6e-9682829b5701' User entered 'No (N)'	System	04 Apr 2021 13:03:03
	System	04 Apr 2021 13:03:03

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-04-04T09:02:57-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '30d9eb9c-a003-4f83-9f6e-9682829b5701' User entered 'No (N)'	System	04 Apr 2021 13:03:03

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-04-04T09:03:00-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '30d9eb9c-a003-4f83-9f6e-9682829b5701' User entered '04 Apr 2021 09:03:00'	System	04 Apr 2021 13:03:03
	System	04 Apr 2021 13:03:03

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-04-12T06:27:18-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '22692a37-6816-43ee-9304-b0b68e567e2f' User entered 'No (N)'	System	12 Apr 2021 10:27:30
	System	12 Apr 2021 10:27:30

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-04-12T06:27:22-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '22692a37-6816-43ee-9304-b0b68e567e2f' User entered 'No (N)'	System	12 Apr 2021 10:27:30
	System	12 Apr 2021 10:27:30

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-04-12T06:27:28-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '22692a37-6816-43ee-9304-b0b68e567e2f' User entered '12 Apr 2021 06:27:28'	System	12 Apr 2021 10:27:30
	System	12 Apr 2021 10:27:30

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-04-18T06:02:34-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '22b350f5-8cf1-449a-8dc4-4b8d6195cb55'	System	18 Apr 2021 10:02:47
User entered 'No (N)'	System	18 Apr 2021 10:02:47

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-04-18T06:02:38-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '22b350f5-8cf1-449a-8dc4-4b8d6195cb55'	System	18 Apr 2021 10:02:47
User entered 'No (N)'	System	18 Apr 2021 10:02:47

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-04-18T06:02:42-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '22b350f5-8cf1-449a-8dc4-4b8d6195cb55'	System	18 Apr 2021 10:02:47
User entered '18 Apr 2021 06:02:42'	System	18 Apr 2021 10:02:47

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-04-25T00:26:48-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'b5b85728-7a18-416a-91cf-f975f7bdb461' User entered 'No (N)'	System	25 Apr 2021 04:27:04
	System	25 Apr 2021 04:27:04

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-04-25T00:26:55-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'b5b85728-7a18-416a-91cf-f975f7bdb461' User entered 'No (N)'	System	25 Apr 2021 04:27:04
	System	25 Apr 2021 04:27:04

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-04-25T00:26:58-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'b5b85728-7a18-416a-91cf-f975f7bdb461' User entered '25 Apr 2021 00:26:58'	System	25 Apr 2021 04:27:04
	System	25 Apr 2021 04:27:04

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-05-02T17:39:02-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '40e9e2db-3d0d-47bb-86c6-4918c2e2a623'	System	02 May 2021 21:39:14
User entered 'No (N)'	System	02 May 2021 21:39:14

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[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 (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-05-02T17:39:06-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '40e9e2db-3d0d-47bb-86c6-4918c2e2a623'	System	02 May 2021 21:39:14
User entered 'No (N)'	System	02 May 2021 21:39:14

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-05-02T17:39:10-04:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: '40e9e2db-3d0d-47bb-86c6-4918c2e2a623'	System	02 May 2021 21:39:14
User entered '02 May 2021 17:39:10'	System	02 May 2021 21:39:14

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 06:57:54

US3712064

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:57:54
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 06:57:54

US3712064

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:24:11

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)	24 Apr 2021 22:45:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-03-01T06:03:38-05:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'df9835e9-6239-4287-9596-d4804cca4fb4'	System	14 Mar 2021 09:41:18
User entered 'No (N)'	System	14 Mar 2021 09:41:18

US3712064

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:24:11

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:45:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB53F3B0-BB2A-499D-9058-68AB7DAE4488)', Time: '2021-03-01T06:03:42-05:00', User OID: 'PatientReportedOutcome (US3712064)', ODM File OID: 'df9835e9-6239-4287-9596-d4804cca4fb4'	System	14 Mar 2021 09:41:18
User entered '01 Mar 2021 06:03:42'	System	14 Mar 2021 09:41:18

US3712064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:08
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:29:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:57:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 14:23:44

US3712064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:08
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:29:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:57:13
User entered '08 Dec 2020'	(b) (4), (b) (6)	04 Jan 2021 14:23:44

US3712064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:08
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:29:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:57:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Jan 2021 14:23:44

US3712064

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:08
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:29:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:57:13
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 14:23:44

US3712064

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:08
User signature succeeded.	William Smith (b) (4)	10 Mar 2021 02:29:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:57:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 14:23:48

US3712064

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:04:08
User entered 'I'	System	04 Jan 2021 14:23:48

US3712064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:19
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:58:25
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 29-Jan-2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 10:52:47
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 29-Jan-2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'updating' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 18:55:54
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 29-Jan-2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 10:33:12
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	22 Jan 2021 12:59:01
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	22 Jan 2021 12:58:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 12:58:55

US3712064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:37:54
User closed query 'Please confirm as date of call in source appears to be 16Jan2021.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 21:37:00
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
Query 'Please confirm as date of call in source appears to be 16Jan2021.' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:58:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Mar 2021 19:58:21
User entered '16 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 19:58:21
User opened query 'Please confirm as date of call in source appears to be 16Jan2021.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 19:25:40
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:58:25
User entered '11 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 12:58:55

US3712064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:19
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:58:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Jan 2021 12:59:01
reason for change: Data Entry Error		
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 12:58:55

US3712064

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:19
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:58:25
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 12:58:55

US3712064

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:19
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:00:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 12:59:03

US3712064

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:19
User entered 'I'	System	22 Jan 2021 12:59:03

US3712064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:19
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:02:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 23:01:50

US3712064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:19
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:02:06
User entered '10 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 23:01:50

US3712064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:19
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:02:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Feb 2021 23:01:50

US3712064

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:19
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:02:06
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 23:01:50

US3712064

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:19
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:15:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 23:02:14

US3712064

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:19
User entered 'I'	System	22 Feb 2021 23:02:14

US3712064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:39:12
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 11:49:46

US3712064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:39:12
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 11:49:46

US3712064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:39:12
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 11:49:46

US3712064

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:39:12
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 11:49:46

US3712064

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:39:15
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 11:49:51

US3712064

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:58:19
User entered 'I'	System	23 Mar 2021 11:49:51

US3712064

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

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:38:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 18:59:16

US3712064

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

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:38:22
User entered '29 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 18:59:16

US3712064

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

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:38:22
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Feb 2021 18:59:16

US3712064

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

Form: Visit Date

Generated On: 10 Jun 2021 09:24:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User entered 'UNBLND_DECIDE'	System	05 Feb 2021 18:59:16

US3712064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:24:11

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:39:45
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 19:54:59
User entered '29 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 19:54:59
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:40:30
User entered '06 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 19:12:52

US3712064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:24:11

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:44:56

US3712064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:24:11

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:40:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 19:12:52

US3712064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:24:11

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:44:56

US3712064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:24:11

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:40:30
User entered '29 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 19:12:52

US3712064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:24:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:40:30
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	05 Feb 2021 19:12:52

US3712064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:24:11

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:40:30
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	05 Feb 2021 19:12:52

US3712064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:24:11

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:40:30
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	05 Feb 2021 19:12:52

US3712064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:24:11

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:40:30
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 19:12:52

US3712064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:24:11

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User entered empty.	System	05 Feb 2021 19:12:52

US3712064

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

Form: Unblinding

Generated On: 10 Jun 2021 09:24:11

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User entered empty.	System	05 Feb 2021 19:12:52

US3712064

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:42:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 19:06:23

US3712064

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:42:30
User entered '29 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 19:06:23

US3712064

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:42:30
User entered '11:02'	(b) (4), (b) (6)	05 Feb 2021 19:06:23

US3712064

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User entered '29 Jan 2021 11:02'	System	05 Feb 2021 19:06:23

US3712064

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:24:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 19:06:32

US3712064

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:16
User entered '29 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 19:06:32

US3712064

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:24:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:44:16
User entered '11:05'	(b) (4), (b) (6)	05 Feb 2021 19:06:32

US3712064

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:24:11

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:32:58
User entered '29 Jan 2021 11:05'	System	05 Feb 2021 19:06:32

US3712064

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:24:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:21:12
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:27:18
User signature succeeded.	William Smith (b) (4)	12 Mar 2021 22:20:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 18:56:32
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 14:53:54

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Feb 2021 18:58:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Feb 2021 18:58:54
Data point term sent to Coder	System	05 Feb 2021 18:58:45
User entered 'left hip pain'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered '15 Dec 2020'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 18:58:04

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User entered empty.	System	05 Feb 2021 18:58:04

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:40:24
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Apr 2021 13:13:30
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:46:57
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 12:46:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 12:46:27
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 03:39:46
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:40:22
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:46:27
User entered '05 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 12:46:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 18:58:04

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 18:58:04

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User entered empty.	System	05 Feb 2021 18:58:04

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:40:20
User closed query 'Please have PI/ Sub-I review this as the subject eventually had a surgical repair, mild may be incorrect.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 21:40:19
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
Query 'Please have PI/ Sub-I review this as the subject eventually had a surgical repair, mild may be incorrect.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 12:47:12
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 12:46:27
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 12:46:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:20:21
User opened query 'Please have PI/ Sub-I review this as the subject eventually had a surgical repair, mild may be incorrect.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 17:13:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 18:58:04

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 18:58:04

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 18:58:04

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 18:58:04

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

US3712064

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered 'None (NONE)'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered 'l'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:40:32
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:46:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 12:46:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	05 Feb 2021 18:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 18:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:20:21
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 18:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User entered '0'	System	05 Feb 2021 18:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26
User entered '1'	System	05 Feb 2021 18:58:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:59:26

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:24:53
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:46:49
User entered	System	18 Feb 2021 19:46:46
'USA-US068-2021-mRNA-1273-P301000013'		
User entered 'New'	(b) (4), (b) (6)	18 Feb 2021 19:46:46

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Adverse event](#)

Audit	User	Time (GMT)
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)	19 Apr 2021 20:06:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:06:46
User signature succeeded.	William Smith (b) (4) (b) (4)	18 Apr 2021 23:28:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:27:34
Data point term sent to Coder	System	15 Apr 2021 11:55:42
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 11:55:34
Coding entries removed.	(b) (4), (b) (6)	15 Apr 2021 11:55:34
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 11:55:34
User entered 'LEFT HIP degenerative joint disease with arthritis' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 11:55:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:40:42
User signature succeeded.	William Smith (b) (4) (b) (4)	05 Apr 2021 00:15:06
User closed query 'PV Query: The event term is reported as a procedure. Please consider updating event term of disease progression to include disease progression of (underlying condition).' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 18:03:04
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:53:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:53:37
Data point term sent to Coder	System	31 Mar 2021 13:52:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:52:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:52:33

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'For coding purposes, LEFT HIP PLACEMENT is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from System).	System	31 Mar 2021 13:51:53
Query 'For coding purposes, LEFT HIP PLACEMENT is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 13:51:53
Data point term sent to Coder	System	31 Mar 2021 13:51:50
Query 'PV Query: The event term is reported as a procedure. Please consider updating event term of disease progression to include disease progression of (underlying condition).' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 13:51:30
DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 13:51:14
Coding entries removed.	(b) (4), (b) (6)	31 Mar 2021 13:51:14
User entered 'LEFT HIP pain' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 13:51:14
User opened query 'For coding purposes, LEFT HIP PLACEMENT is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from System).	Coder Import (b) (4)	20 Mar 2021 21:37:39
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User opened query 'PV Query: The event term is reported as a procedure. Please consider updating event term of disease progression to include disease progression of (underlying condition).' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 17:29:53
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)	18 Feb 2021 16:59:52

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	18 Feb 2021 16:59:52
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	18 Feb 2021 16:59:40
User entered 'LEFT HIP REPLACEMENT'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered 'No (N)'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered 'No (N)'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:28:04
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User closed query 'PV Query: Please confirm if event start date should be 12 Jan 2021. It seems the reason for the hip replacement was due to hip pain which started on 12 Jan 2021.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:03:07
Query 'PV Query: Please confirm if event start date should be 12 Jan 2021. It seems the reason for the hip replacement was due to hip pain which started on 12 Jan 2021.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 13:52:06
DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 13:51:14
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 13:51:14
User opened query 'PV Query: Please confirm if event start date should be 12 Jan 2021. It seems the reason for the hip replacement was due to hip pain which started on 12 Jan 2021.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 15:11:14
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered '04 Feb 2021'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	24 Feb 2021 18:24:53
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered 'No (N)'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered '05 Feb 2021'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:41:00
User closed query 'Please confirm, as it seems to be noted this was graded as "moderate" on the SAE form. If confirmed, please update.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 21:40:59
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
Query 'Please confirm, as it seems to be noted this was graded as "moderate" on the SAE form. If confirmed, please update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 18:53:37
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 18:53:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 18:53:30
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User opened query 'Please confirm, as it seems to be noted this was graded as "moderate" on the SAE form. If confirmed, please update.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 18:24:22
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered '0'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered '0'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered '04 Feb 2021'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety). Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Emailed discharge summary right before answering this query :)' (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:52:49
	(b) (4), (b) (6)	01 Mar 2021 19:00:09
	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety). User entered '05 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 17:31:12
	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered 'No (N)'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered '0'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered '0'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered '0'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
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.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:03:24
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:24:53
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)	24 Feb 2021 17:29:18
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:24:53
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:41:29
User closed query 'Please review dates for February as 2021 rather than 2020.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 21:41:20
User closed query 'Per DM CLR: Narrative indicates that the subject was given NORCO 7.5MG-325MG Q4HR PRN, DEXTROSE IN WATER IV 50ML/HR, ANCEF 2G IV X 1, ANCEF 1G X 2, METHYLPHENIDATE 10MG PO X 3. However, there is no corresponding Concomitant Medications record that match the information. Please update to record the corresponding medications as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 04:23:13
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed before or during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 12:51:45
Query 'PV Query: Please provide the results of any COVID-19 testing performed before or during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'There is no record in medical records of any covid-19 testing ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 12:47:52
Query 'Per DM CLR: Narrative indicates that the subject was given NORCO 7.5MG-325MG Q4HR PRN, DEXTROSE IN WATER IV 50ML/HR, ANCEF 2G IV X 1, ANCEF 1G X 2, METHYLPHENIDATE 10MG PO X 3. However, there is no corresponding Concomitant Medications record that match the information. Please update to record the corresponding medications as appropriate. Otherwise, clarify.' answered with 'updating' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 14:03:11
Query 'Please review dates for February as 2021 rather than 2020.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 13:52:21
DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 13:51:14

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTED TO UTM ON 04 FEB 2021 FOR LEFT HIP REPLACEMENT WITH (b) (6) . HE WAS ADMITTED TO THE HOSPITAL OVER NIGHT FOR ONE NIGHT AND WAS DISCHARGED ON 05 FEB 2021.
SUBJECT REPORTED TO TOC ON 12 JAN 2021, COMPLAINING OF 5/10 LEFT HIP PAIN. LEFT HIP X-RAY SHOWED A SIGNIFICANT DEGENERATION OF LEFT HIP WITH CYSTIC CHANGES, LOSS OF JOINT SPACE AND OSTEOARTHRITIS. THERE IS ONLY ABOUT 1MM OF JOINT SPACE REMAINING THROUGH OUT THE HIP. ON 04 FEB 2021 SUBJECT HAD A LEFT TOTAL HIP ARTHROPLASTY THROUGH AN ANTERIOR APPROACH. SPINAL ANESTHESIA WAS USED. BLOOD LOSS WAS MINIMAL. MEDIUM HEMOVAC DRAIN WAS PLACED. SUBJECT HAD NO COMPLICATIONS AND RECOVERED ACCORDING TO ORTHOPEDIST'S PLAN. SUBJECT CONTINUES TO RECOVER WITHOUT PAIN OR COMPLICATIONS. SUBJECT RECEIVED NORCO 7.5MG-325MG Q4HR PRN, ELIQUIS 2.5MG BID X 35 DAYS, ZOFRAN 4MG Q12HR PRN, DEXTROSE IN WATER IV 50ML/HR, ANCEF 2G IV X 1, ANCEF 1G X 2, METHYLPHENIDATE 10MG PO X 3. LAB WORK SHOWED: SODIUM 134, POTASSIUM 134, CHLORIDE 98, C02 32, BUN 17, CREATININE 0.95, CALCIUM 9.0, HEMOGLOBIN 12.5, HEMATOCRIT 36.2, WBC 13.1, PLATELET 197, RBC 4.12, GLUCOSE 159. SUBJECT WAS DISCHARGED HOME WITHOUT COMPLAINT ON 05 FEB 2021.' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 13:51:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative indicates that the subject was given NORCO 7.5MG-325MG Q4HR PRN, DEXTROSE IN WATER IV 50ML/HR, ANCEF 2G IV X 1, ANCEF 1G X 2, METHYLPHENIDATE 10MG PO X 3. However, there is no corresponding Concomitant Medications record that match the information. Please update to record the corresponding medications as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 13:46:32
Query 'PV Query: Subject has a medical history of total hip arthroplasty performed Jun2019. Please confirm if this was the left or right hip.' canceled (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 18:03:34
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:24:53
User opened query 'PV Query: Subject has a medical history of total hip arthroplasty performed Jun2019. Please confirm if this was the left or right hip.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 17:29:33
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed before or during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 17:29:02
User opened query 'Please review dates for February as 2021 rather than 2020.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 16:04:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTED TO UTMIC ON 04 FEB 2020 FOR LEFT HIP REPLACEMENT WITH (b) (6) . HE WAS ADMITTED TO THE HOSPITAL OVER NIGHT FOR ONE NIGHT AND WAS DISCHARGED ON 05 FEB 2020. />Subject reported to TOC on 12 JAN 2021, complaining of 5/10 left hip pain. Left hip X-ray showed a significant degeneration of left hip with cystic changes, loss of joint space and osteoarthritis. There is only about 1mm of joint space remaining through out the hip. On 04 FEB 2021 subject had a left total hip arthroplasty through an anterior approach. Spinal anesthesia was used. Blood loss was minimal. Medium hemovac drain was placed. Subject had no complications and recovered according to Orthopedist's plan. Subject continues to recover without pain or complications. Subject received Norco 7.5mg-325mg Q4hr PRN, eliquis 2.5mg BID x 35 days, Zofran 4mg Q12hr prn, dextrose in water IV 50ml/hr, ancef 2g iv x 1, ancef 1g x 2, methylphenidate 10mg po x 3. Lab work showed: sodium 134, potassium 134, chloride 98, c02 32, BUN 17, creatinine 0.95, calcium 9.0, hemoglobin 12.5, hematocrit 36.2, wbc 13.1, platelet 197, rbc 4.12, glucose 159. Subject was discharged home without complaint on 05 FEB 2021.' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 15:38:46
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Feb 2021 17:46:57
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	18 Feb 2021 17:46:57
User entered 'subject reported to UTMIC on 04 FEB 2020 for left hip replacement with (b) (6) He was admitted to the hospital over night for one night and was discharged on 05 FEB 2020.' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 17:46:57
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Feb 2021 16:58:47

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Feb 2021 16:58:47

US3712064

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
User entered '0'	System	18 Feb 2021 16:58:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:24:11

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:21:12
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:28:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:39:56

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:41:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:41:44
Data point term sent to Coder	System	18 Sep 2020 19:40:59
User entered 'hydrochlorothiazide'	(b) (4), (b) (6)	18 Sep 2020 19:40:43

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:40:43

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'hypertension'	(b) (4), (b) (6)	18 Sep 2020 19:40:43

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:59:48
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '25'	(b) (4), (b) (6)	18 Sep 2020 19:40:43

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'mg (mg)'	(b) (4), (b) (6)	18 Sep 2020 19:40:43

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:40:43

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'once daily (QD)'	(b) (4), (b) (6)	18 Sep 2020 19:40:43

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:40:43

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	18 Sep 2020 19:40:43

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:40:43

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'un UNK 2009'	(b) (4), (b) (6)	18 Sep 2020 19:40:43

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:40:43

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:40:43

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:40:43

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:40:43

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:40:43

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:40:43

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:40:43

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
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: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:42:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:42:47
Data point term sent to Coder	System	18 Sep 2020 19:42:02
User entered 'Ibuprofen'	(b) (4), (b) (6)	18 Sep 2020 19:41:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:41:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'osteoarthritis'	(b) (4), (b) (6)	18 Sep 2020 19:41:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '600'	(b) (4), (b) (6)	18 Sep 2020 19:41:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'mg (mg)'	(b) (4), (b) (6)	18 Sep 2020 19:41:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:41:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'once daily (QD)'	(b) (4), (b) (6)	18 Sep 2020 19:41:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:41:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	18 Sep 2020 19:41:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:41:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'un UNK 2010'	(b) (4), (b) (6)	18 Sep 2020 19:41:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:41:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:41:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:41:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:41:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:41:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:41:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:41:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: METHYLPHENIDATE HYDROCHLORIDE, PRODUCTSYNONYM: RITALIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 19:42:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 19:42:46
Data point term sent to Coder	System	18 Sep 2020 19:42:03
User entered 'ritalin'	(b) (4), (b) (6)	18 Sep 2020 19:41:51

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:41:51

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'adult add'	(b) (4), (b) (6)	18 Sep 2020 19:41:51

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '10'	(b) (4), (b) (6)	18 Sep 2020 19:41:51

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'mg (mg)'	(b) (4), (b) (6)	18 Sep 2020 19:41:51

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:41:51

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'once daily (QD)'	(b) (4), (b) (6)	18 Sep 2020 19:41:51

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:41:51

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	18 Sep 2020 19:41:51

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:41:51

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'un UNK 2015'	(b) (4), (b) (6)	18 Sep 2020 19:41:51

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:41:51

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:41:51

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:41:51

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:41:51

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:41:51

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:41:51

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:41:51

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med#3 RITALIN (UN UNK2015-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:06:00
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med#3 RITALIN (UN UNK2015-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'dosages differ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 13:30:48
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med#3 RITALIN (UN UNK2015-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 09:32:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: METHYLPHENIDATE HYDROCHLORIDE, PRODUCTSYNONYM: RITALIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Sep 2020 06:22:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Sep 2020 06:22:47
Data point term sent to Coder	System	18 Sep 2020 19:43:04
User entered 'RITALIN er'	(b) (4), (b) (6)	18 Sep 2020 19:42:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:42:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'adult add'	(b) (4), (b) (6)	18 Sep 2020 19:42:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '20'	(b) (4), (b) (6)	18 Sep 2020 19:42:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'mg (mg)'	(b) (4), (b) (6)	18 Sep 2020 19:42:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:42:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'once daily (QD)'	(b) (4), (b) (6)	18 Sep 2020 19:42:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:42:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	18 Sep 2020 19:42:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:42:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'un UNK 2015'	(b) (4), (b) (6)	18 Sep 2020 19:42:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:42:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:42:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:42:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:42:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:42:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:42:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:42:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:44:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:44:44
Data point term sent to Coder	System	18 Sep 2020 19:44:05
User entered 'vitamin d3'	(b) (4), (b) (6)	18 Sep 2020 19:43:10

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. You may reach out to CRA for assistance if needed. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:06:29
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. You may reach out to CRA for assistance if needed. Update as appropriate.' answered with 'data updated per ECCGS' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 13:30:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 13:30:06
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. You may reach out to CRA for assistance if needed. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 09:33:39
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:43:10

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'supplement'	(b) (4), (b) (6)	18 Sep 2020 19:43:10

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '1000'	(b) (4), (b) (6)	18 Sep 2020 19:43:10

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'IU (IU)'	(b) (4), (b) (6)	18 Sep 2020 19:43:10

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:43:10

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'once daily (QD)'	(b) (4), (b) (6)	18 Sep 2020 19:43:10

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:43:10

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	18 Sep 2020 19:43:10

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:43:10

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'un UNK 2011'	(b) (4), (b) (6)	18 Sep 2020 19:43:10

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 19:43:10

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 19:43:10

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:43:10

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 19:43:10

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:43:10

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:43:10

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:43:10

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:34
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 14:06:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 14:06:33
Data point term sent to Coder	System	31 Mar 2021 14:06:10
Coding entries removed.	(b) (4), (b) (6)	31 Mar 2021 14:05:11
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 11:28:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 11:28:58
Data point term sent to Coder	System	09 Nov 2020 17:54:33
User entered 'influenza vaccine'	(b) (4), (b) (6)	09 Nov 2020 17:53:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:34
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 17:53:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:34
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'preventive health'	(b) (4), (b) (6)	09 Nov 2020 17:53:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:34
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
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) (6)	07 Jan 2021 15:57:02
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 'updated' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 21:12:23
User entered '0.5' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 21:12:03
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).	(b) (4), (b) (6)	22 Dec 2020 02:50:30
User entered '5'	(b) (4), (b) (6)	09 Nov 2020 17:53:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:34
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'mL (mL)'	Tiffany (b) (4), (b) (6)	09 Nov 2020 17:53:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:34
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 17:53:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:34
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'once (ONCE)'	(b) (4), (b) (6)	09 Nov 2020 17:53:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:34
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 17:53:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:34
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:19:21
User closed query 'Please review and confirm route of administration as this is not an expected route.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 21:19:20
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
Query 'Please review and confirm route of administration as this is not an expected route.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 14:05:16
DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 14:05:11
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:05:11
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User opened query 'Please review and confirm route of administration as this is not an expected route.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 18:43:20
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	09 Nov 2020 17:53:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:34
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 17:53:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:34
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '02 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 17:53:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:34
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 17:53:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:34
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 17:53:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:34
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '02 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 17:53:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:34
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 17:53:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:34
User entered empty.	System	09 Nov 2020 17:53:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:34
User entered empty.	System	09 Nov 2020 17:53:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:34
User entered empty.	System	09 Nov 2020 17:53:47

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:38
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 15:18:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 15:18:42
Data point term sent to Coder	System	05 Feb 2021 18:59:45
User entered 'tramadol'	(b) (4), (b) (6)	05 Feb 2021 18:59:00

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:38
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 18:59:00

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:38
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'left hip pain'	(b) (4), (b) (6)	05 Feb 2021 18:59:00

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:38
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '50'	(b) (4), (b) (6)	05 Feb 2021 18:59:00

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:38
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Feb 2021 18:59:00

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:38
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 18:59:00

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:19:39
User closed query 'Please confirm frequency' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 21:19:29
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
Query 'Please confirm frequency' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:06:47
DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 14:06:39
User entered 'as needed (PRN)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:06:39
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User opened query 'Please confirm frequency' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 18:44:04
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Feb 2021 18:59:00

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:38
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 18:59:00

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:38
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Feb 2021 18:59:00

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:38
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 18:59:00

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:38
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '22 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 18:59:00

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:38
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 18:59:00

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:38
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 18:59:00

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:38
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '27 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 18:59:00

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:38
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 18:59:00

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:38
User entered empty.	System	31 Mar 2021 14:06:39
User entered '1'	System	05 Feb 2021 18:59:00

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:38
User entered empty.	System	31 Mar 2021 14:06:39
User entered '1'	System	05 Feb 2021 18:59:00

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:38
User entered empty.	System	31 Mar 2021 14:06:39
User entered '804 (804)'	System	05 Feb 2021 18:59:00

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Feb 2021 19:03:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Feb 2021 19:03:01
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:46:18
Data point term sent to Coder	System	23 Feb 2021 15:40:52
User entered 'zofran'	(b) (4), (b) (6)	23 Feb 2021 15:40:50

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 15:40:50

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'left hip replacement'	(b) (4), (b) (6)	23 Feb 2021 15:40:50

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '4'	(b) (4), (b) (6)	23 Feb 2021 15:40:50

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Feb 2021 15:40:50

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:40:50

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'as needed (PRN)'	(b) (4), (b) (6)	23 Feb 2021 15:40:50

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:40:50

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Feb 2021 15:40:50

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:40:50

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '04 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 15:40:50

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 15:40:50

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 15:40:50

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '07 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 15:40:50

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:43
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 15:40:50

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:43
User entered empty.	System	23 Feb 2021 15:40:50

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:43
User entered empty.	System	23 Feb 2021 15:40:50

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:43
User entered empty.	System	23 Feb 2021 15:40:50

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:19:50
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 13:45:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 13:45:31
Data point term sent to Coder	System	01 Apr 2021 12:51:25
User entered 'HYDROCODONEACETAMINOPHEN (NORCO)'	(b) (4), (b) (6)	01 Apr 2021 12:50:39
reason for change: Data Entry Error		
Data point term sent to Coder	System	31 Mar 2021 14:10:13
DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 14:09:59
Coding entries removed.	(b) (4), (b) (6)	31 Mar 2021 14:09:59
User entered 'HYDROCODONEacetaminophen' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:09:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 06:42:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 06:42:07
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:46:18
Data point term sent to Coder	System	23 Feb 2021 15:41:54
User entered 'hydrocodone'	(b) (4), (b) (6)	23 Feb 2021 15:41:27

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:48
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 15:41:27

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:48
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'left hip replacement'	(b) (4), (b) (6)	23 Feb 2021 15:41:27

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:48
User closed query 'Per DM CLR : Please note that the dosage recorded in the Dose field pertains to a combination drug. Please confirm if this is a combination drug and update Medication Name to reflect the Generic Name, Active Ingredients or Trade Name that is appropriate with the dose recorded. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 12:03:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
Query 'Per DM CLR : Please note that the dosage recorded in the Dose field pertains to a combination drug. Please confirm if this is a combination drug and update Medication Name to reflect the Generic Name, Active Ingredients or Trade Name that is appropriate with the dose recorded. ' answered with 'added to term name ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:10:05
User opened query 'Per DM CLR : Please note that the dosage recorded in the Dose field pertains to a combination drug. Please confirm if this is a combination drug and update Medication Name to reflect the Generic Name, Active Ingredients or Trade Name that is appropriate with the dose recorded. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 03:56:55
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '7.5/325'	(b) (4), (b) (6)	23 Feb 2021 15:41:27

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:48
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Feb 2021 15:41:27

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:48
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:41:27

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:48
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'as needed (PRN)'	(b) (4), (b) (6)	23 Feb 2021 15:41:27

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:48
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:41:27

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:48
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Feb 2021 15:41:27

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:48
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:41:27

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:48
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '04 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 15:41:27

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:48
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 15:41:27

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:48
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 15:41:27

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:48
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '07 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 15:41:27

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:48
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 15:41:27

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:48
User entered empty.	System	23 Feb 2021 15:41:27

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:48
User entered empty.	System	23 Feb 2021 15:41:27

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:48
User entered empty.	System	23 Feb 2021 15:41:27

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:42:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:42:00
Data point term sent to Coder	System	23 Feb 2021 15:41:53
User entered 'eliquis'	(b) (4), (b) (6)	23 Feb 2021 15:41:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 15:41:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'left hip replacement'	(b) (4), (b) (6)	23 Feb 2021 15:41:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '2.5'	(b) (4), (b) (6)	23 Feb 2021 15:41:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Feb 2021 15:41:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:41:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'twice daily (BID)'	(b) (4), (b) (6)	23 Feb 2021 15:41:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:41:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Feb 2021 15:41:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:41:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '04 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 15:41:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 15:41:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:53
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:28:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:28:54
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 11:48:46
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 11:48:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 11:48:46
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 15:41:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:53
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:28:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:28:52
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 11:48:46
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 11:48:46
User entered '11 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 11:48:46
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:41:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:53
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 15:41:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:53
User entered '2'	System	23 Feb 2021 15:41:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:53
User entered '1'	System	23 Feb 2021 15:41:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:53
User entered '804 (804)'	System	23 Feb 2021 15:41:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:59
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:44:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Feb 2021 15:44:00
Data point term sent to Coder	System	23 Feb 2021 15:42:55
User entered 'tylenol'	(b) (4), (b) (6)	23 Feb 2021 15:42:08

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:59
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 15:42:08

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:59
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'left hip replacement'	(b) (4), (b) (6)	23 Feb 2021 15:42:08

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:59
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '1000'	(b) (4), (b) (6)	23 Feb 2021 15:42:08

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:59
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Feb 2021 15:42:08

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:59
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:42:08

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:59
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'as needed (PRN)'	(b) (4), (b) (6)	23 Feb 2021 15:42:08

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:59
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:42:08

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:59
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Feb 2021 15:42:08

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:59
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:42:08

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:59
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '04 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 15:42:08

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:59
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 15:42:08

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:21:54
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 12:04:08
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 12:49:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 12:49:23
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 03:58:30
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 15:42:08

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:21:55
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:49:23
User entered '10 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 12:49:23
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 15:42:08

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:59
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:46:18
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 15:42:08

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:59
User entered empty.	System	23 Feb 2021 15:42:08

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:59
User entered empty.	System	23 Feb 2021 15:42:08

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:24:59
User entered empty.	System	23 Feb 2021 15:42:08

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:05
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE IN WATER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:45:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:45:40
User signature succeeded.	William Smith (b) (4) (b) (4)	05 Apr 2021 00:15:06
Data point term sent to Coder	System	01 Apr 2021 12:54:26
User entered 'dextrose in water'	(b) (4), (b) (6)	01 Apr 2021 12:53:40

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:05
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:53:40

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:05
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'left hip replacement'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:53:40

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:05
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '50'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:53:40

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:05
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:53:40

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:05
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'ml/hr'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:53:40

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:05
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:53:40

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:05
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'continuous'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:53:40

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:05
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:53:40

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:05
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:53:40

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:05
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:53:40

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:05
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:53:40

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:05
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:53:40

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:05
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:53:40

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:05
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:53:40

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:05
User entered empty.	System	01 Apr 2021 12:53:40

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:05
User entered empty.	System	01 Apr 2021 12:53:40

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:05
User entered empty.	System	01 Apr 2021 12:53:40

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFZOLIN SODIUM, PRODUCTSYNONYM: ANCEF [CEFZOLIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:15:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:15:08
User signature succeeded.	William Smith (b) (4) (b) (4)	05 Apr 2021 00:15:06
Data point term sent to Coder	System	01 Apr 2021 12:55:27
User entered 'ancef'	(b) (4), (b) (6)	01 Apr 2021 12:54:30

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:54:30

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'left hip replacement'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:54:30

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '2'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:54:30

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:54:30

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:54:30

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:54:30

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:54:30

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:54:30

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:54:30

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:54:30

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:54:30

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:54:30

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:54:30

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:54:30

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:10
User entered empty.	System	01 Apr 2021 12:54:30

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:10
User entered empty.	System	01 Apr 2021 12:54:30

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:10
User entered empty.	System	01 Apr 2021 12:54:30

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:14
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFZOLIN SODIUM, PRODUCTSYNONYM: ANCEF [CEFZOLIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:15:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:15:08
User signature succeeded.	William Smith (b) (4) (b) (4)	05 Apr 2021 00:15:06
Data point term sent to Coder	System	01 Apr 2021 12:56:27
User entered 'ancef'	(b) (4), (b) (6)	01 Apr 2021 12:56:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:14
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:56:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:14
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'left hip replacement'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:56:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:14
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'l'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:56:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:14
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:56:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:14
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:56:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:14
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:56:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:14
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '2 doses'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:56:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:14
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:56:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:14
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:56:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:14
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:56:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:14
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:56:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:14
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:56:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:14
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:56:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:14
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:56:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:14
User entered empty.	System	01 Apr 2021 12:56:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:14
User entered empty.	System	01 Apr 2021 12:56:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:14
User entered empty.	System	01 Apr 2021 12:56:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: METHYLPHENIDATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:44:45
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 Apr 2021 12:44:45
User signature succeeded.	William Smith (b) (4) (b) (4)	05 Apr 2021 00:15:06
Data point term sent to Coder	System	01 Apr 2021 12:57:28
User entered 'methylphenidate'	(b) (4), (b) (6)	01 Apr 2021 12:57:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:57:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'left hip replacement'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:57:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '10'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:57:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:57:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:57:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:57:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '3 doses'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:57:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:57:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:57:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:57:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:57:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:57:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:57:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:06:33
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:57:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:20
User entered empty.	System	01 Apr 2021 12:57:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:20
User entered empty.	System	01 Apr 2021 12:57:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:20
User entered empty.	System	01 Apr 2021 12:57:01

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:24
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 09:53:12
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 Apr 2021 09:53:12
Data point term sent to Coder	System	19 Apr 2021 16:00:56
User entered 'docusate'	(b) (4), (b) (6)	19 Apr 2021 16:00:53

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:24
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 17:09:33
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 16:00:53

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:24
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'prevention of constipation while hospitalized'	(b) (4), (b) (6)	19 Apr 2021 16:00:53

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:24
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '100'	(b) (4), (b) (6)	19 Apr 2021 16:00:53

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:24
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Apr 2021 16:00:53

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:24
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:00:53

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:24
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Apr 2021 16:00:53

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:24
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:00:53

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:24
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Apr 2021 16:00:53

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:24
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:00:53

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:24
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 16:00:53

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:24
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 16:00:53

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:24
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 16:00:53

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:24
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '05 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 16:00:53

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:24
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 16:00:53

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:24
User entered '1'	System	19 Apr 2021 16:00:53

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:24
User entered '1'	System	19 Apr 2021 16:00:53

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:24
User entered '804 (804)'	System	19 Apr 2021 16:00:53

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:30
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 08:36:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 08:36:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:45:46
Data point term sent to Coder	System	19 Apr 2021 16:04:02
User entered 'senna (senokot)'	(b) (4), (b) (6)	19 Apr 2021 16:03:12

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:30
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 16:03:12

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:30
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'prevention of constipation while hospitalized'	(b) (4), (b) (6)	19 Apr 2021 16:03:12

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:30
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '50/8.6'	(b) (4), (b) (6)	19 Apr 2021 16:03:12

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:30
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Apr 2021 16:03:12

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:30
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:03:12

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:30
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Apr 2021 16:03:12

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:30
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:03:12

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:30
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Apr 2021 16:03:12

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:30
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:03:12

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:30
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 16:03:12

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:30
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 16:03:12

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:30
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 16:03:12

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:30
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '05 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 16:03:12

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:30
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 16:03:12

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:30
User entered '1'	System	19 Apr 2021 16:03:12

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:30
User entered '1'	System	19 Apr 2021 16:03:12

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:30
User entered '804 (804)'	System	19 Apr 2021 16:03:12

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:35
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
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.	Coder Import (b) (4) (b) (4)	19 Apr 2021 16:09:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 16:09:39
Data point term sent to Coder	System	19 Apr 2021 16:05:04
User entered 'acetaminophen'	(b) (4), (b) (6)	19 Apr 2021 16:04:20

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:35
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 16:04:20

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:35
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'prevention of pain during hospitalization'	(b) (4), (b) (6)	19 Apr 2021 16:04:20

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:35
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '650'	(b) (4), (b) (6)	19 Apr 2021 16:04:20

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:35
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Apr 2021 16:04:20

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:35
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:04:20

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:35
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Apr 2021 16:04:20

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:35
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:04:20

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:35
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Apr 2021 16:04:20

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:35
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:04:20

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:35
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 16:04:20

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:35
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 16:04:20

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:35
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 16:04:20

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:35
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '05 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 16:04:20

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:35
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 16:04:20

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:35
User entered empty.	System	19 Apr 2021 16:04:20

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:35
User entered empty.	System	19 Apr 2021 16:04:20

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:35
User entered empty.	System	19 Apr 2021 16:04:20

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:40
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: CHOLECALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 16:11:14
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 Apr 2021 16:11:14
Data point term sent to Coder	System	19 Apr 2021 16:06:05
User entered 'cholecalciferol'	(b) (4), (b) (6)	19 Apr 2021 16:05:09

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:40
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 16:05:09

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:40
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'supplement'	(b) (4), (b) (6)	19 Apr 2021 16:05:09

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:40
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '2000'	(b) (4), (b) (6)	19 Apr 2021 16:05:09

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:40
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Other (OTHER)'	(b) (4), (b) (6)	19 Apr 2021 16:05:09

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:40
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'units'	(b) (4), (b) (6)	19 Apr 2021 16:05:09

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:40
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Apr 2021 16:05:09

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:40
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:05:09

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:40
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Apr 2021 16:05:09

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:40
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:05:09

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:40
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 16:05:09

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:40
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 16:05:09

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:40
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 16:05:09

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:40
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '05 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 16:05:09

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:40
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 16:05:09

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:40
User entered '1'	System	19 Apr 2021 16:05:09

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:40
User entered '1'	System	19 Apr 2021 16:05:09

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:40
User entered '804 (804)'	System	19 Apr 2021 16:05:09

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 01:49:39
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 01:49:39
Data point term sent to Coder	System	19 Apr 2021 16:07:07
User entered 'bisacodyl'	(b) (4), (b) (6)	19 Apr 2021 16:06:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 16:06:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'prevention of constipation during hospitalization'	(b) (4), (b) (6)	19 Apr 2021 16:06:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '10'	(b) (4), (b) (6)	19 Apr 2021 16:06:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Apr 2021 16:06:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:06:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Apr 2021 16:06:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:06:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Other (OTHER)'	(b) (4), (b) (6)	19 Apr 2021 16:06:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'suppository'	(b) (4), (b) (6)	19 Apr 2021 16:06:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 16:06:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 16:06:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 16:06:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '05 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 16:06:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 16:06:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:44
User entered empty.	System	19 Apr 2021 16:06:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:44
User entered empty.	System	19 Apr 2021 16:06:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:44
User entered empty.	System	19 Apr 2021 16:06:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:49
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 09:52:48
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 09:52:48
Data point term sent to Coder	System	19 Apr 2021 16:56:46
User entered 'diphenhydramine'	(b) (4), (b) (6)	19 Apr 2021 16:56:45

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:49
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 16:56:45

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:49
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'prevention of of allergic reaction while hospitalized '	(b) (4), (b) (6)	19 Apr 2021 16:56:45

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:49
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '25'	(b) (4), (b) (6)	19 Apr 2021 16:56:45

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:49
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Apr 2021 16:56:45

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:49
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:56:45

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:49
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Apr 2021 16:56:45

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:49
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:56:45

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:49
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Apr 2021 16:56:45

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:49
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:56:45

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:49
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 16:56:45

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:49
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 16:56:45

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:49
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 16:56:45

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:49
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '05 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 16:56:45

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:49
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 16:56:45

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:49
User entered empty.	System	19 Apr 2021 16:56:45

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:49
User entered empty.	System	19 Apr 2021 16:56:45

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:49
User entered empty.	System	19 Apr 2021 16:56:45

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 09:52:48
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 09:52:48
Data point term sent to Coder	System	19 Apr 2021 16:57:46
User entered 'diphenhydramine'	(b) (4), (b) (6)	19 Apr 2021 16:57:33

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 16:57:33

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'prevention of of allergic reaction while hospitalized '	(b) (4), (b) (6)	19 Apr 2021 16:57:33

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '12.5'	(b) (4), (b) (6)	19 Apr 2021 16:57:33

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Apr 2021 16:57:33

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:57:33

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Apr 2021 16:57:33

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:57:33

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	19 Apr 2021 16:57:33

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:57:33

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 16:57:33

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 16:57:33

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 16:57:33

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '05 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 16:57:33

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:53
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 16:57:33

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:53
User entered empty.	System	19 Apr 2021 16:57:33

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:53
User entered empty.	System	19 Apr 2021 16:57:33

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:53
User entered empty.	System	19 Apr 2021 16:57:33

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:59
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
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: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:05:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:05:03
Data point term sent to Coder	System	19 Apr 2021 16:59:50
User entered 'normal saline flush'	(b) (4), (b) (6)	19 Apr 2021 16:59:19

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:59
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 16:59:19

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:59
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'prevention of IV clotting while hospitalized'	(b) (4), (b) (6)	19 Apr 2021 16:59:19

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:59
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '10'	(b) (4), (b) (6)	19 Apr 2021 16:59:19

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:59
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'mL (mL)'	(b) (4), (b) (6)	19 Apr 2021 16:59:19

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:59
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:59:19

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:59
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'other (OTHER)'	(b) (4), (b) (6)	19 Apr 2021 16:59:19

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:59
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'every 12 hours'	(b) (4), (b) (6)	19 Apr 2021 16:59:19

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:59
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	19 Apr 2021 16:59:19

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:59
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 16:59:19

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:59
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 16:59:19

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:59
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 16:59:19

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:59
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 16:59:19

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:59
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '05 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 16:59:19

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:59
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 16:59:19

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:59
User entered empty.	System	19 Apr 2021 16:59:19

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:59
User entered empty.	System	19 Apr 2021 16:59:19

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:25:59
User entered empty.	System	19 Apr 2021 16:59:19

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:03
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: CALCIUM COMPOUNDS, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: MAALOX [CALCIUM CARBONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 21:17:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 21:17:37
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 13:45:46
Data point term sent to Coder	System	19 Apr 2021 17:00:51
User entered 'maalox simethicone'	(b) (4), (b) (6)	19 Apr 2021 17:00:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:03
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 17:00:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:03
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'prevention of acid reflux during hospitalized'	(b) (4), (b) (6)	19 Apr 2021 17:00:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:03
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '30'	(b) (4), (b) (6)	19 Apr 2021 17:00:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:03
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'mL (mL)'	(b) (4), (b) (6)	19 Apr 2021 17:00:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:03
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:00:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:03
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'other (OTHER)'	(b) (4), (b) (6)	19 Apr 2021 17:00:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:03
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'every 4 hours as needed'	(b) (4), (b) (6)	19 Apr 2021 17:00:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:03
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Apr 2021 17:00:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:24:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:03
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:00:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:03
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 17:00:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:03
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 17:00:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:03
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:00:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:03
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '05 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 17:00:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:03
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:00:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:03
User entered empty.	System	19 Apr 2021 17:00:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:03
User entered empty.	System	19 Apr 2021 17:00:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:03
User entered empty.	System	19 Apr 2021 17:00:49

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:09
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM OXIDE, PRODUCTSYNONYM: MAG-OX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:03:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:03:56
Data point term sent to Coder	System	19 Apr 2021 17:01:51
User entered 'mag-ox'	(b) (4), (b) (6)	19 Apr 2021 17:01:24

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:09
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 17:01:24

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:09
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'supplement'	(b) (4), (b) (6)	19 Apr 2021 17:01:24

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:09
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '400'	(b) (4), (b) (6)	19 Apr 2021 17:01:24

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:09
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Apr 2021 17:01:24

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:24:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:09
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:01:24

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:09
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Apr 2021 17:01:24

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:09
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:01:24

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:09
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Apr 2021 17:01:24

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:09
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:01:24

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:09
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 17:01:24

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:09
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 17:01:24

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:09
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:01:24

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:09
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '05 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 17:01:24

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:09
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:01:24

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:09
User entered '1'	System	19 Apr 2021 17:01:24

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:09
User entered '1'	System	19 Apr 2021 17:01:24

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:09
User entered '804 (804)'	System	19 Apr 2021 17:01:24

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:13
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
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: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:05:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:05:03
Data point term sent to Coder	System	19 Apr 2021 17:02:53
User entered 'normal saline'	(b) (4), (b) (6)	19 Apr 2021 17:02:22

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:13
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 17:02:22

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:13
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'prevention of dehydration during hospitalization'	(b) (4), (b) (6)	19 Apr 2021 17:02:22

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:13
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '1000'	(b) (4), (b) (6)	19 Apr 2021 17:02:22

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:13
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'mL (mL)'	(b) (4), (b) (6)	19 Apr 2021 17:02:22

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:13
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:02:22

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:13
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Apr 2021 17:02:22

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:13
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:02:22

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:13
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	19 Apr 2021 17:02:22

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:24:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:13
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:02:22

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:13
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 17:02:22

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:13
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 17:02:22

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:13
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:02:22

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:13
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '05 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 17:02:22

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:13
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:02:22

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:13
User entered '1'	System	19 Apr 2021 17:02:22

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:13
User entered '1'	System	19 Apr 2021 17:02:22

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:13
User entered '804 (804)'	System	19 Apr 2021 17:02:22

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:19
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
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: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:05:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:05:03
Data point term sent to Coder	System	19 Apr 2021 17:03:53
User entered 'normal saline flush'	(b) (4), (b) (6)	19 Apr 2021 17:03:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:19
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 17:03:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:19
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'flush of IV while hospitalization'	(b) (4), (b) (6)	19 Apr 2021 17:03:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:19
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '20'	(b) (4), (b) (6)	19 Apr 2021 17:03:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:19
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'mL (mL)'	(b) (4), (b) (6)	19 Apr 2021 17:03:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:19
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:03:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:19
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Apr 2021 17:03:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:19
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:03:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:19
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	19 Apr 2021 17:03:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:19
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:03:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:19
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 17:03:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:19
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 17:03:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:19
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:03:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:19
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '05 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 17:03:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:19
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:03:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:19
User entered '1'	System	19 Apr 2021 17:03:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:19
User entered '1'	System	19 Apr 2021 17:03:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:19
User entered '804 (804)'	System	19 Apr 2021 17:03:32

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:23
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
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.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:05:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:05:03
Data point term sent to Coder	System	19 Apr 2021 17:04:54
User entered 'ondansetron'	(b) (4), (b) (6)	19 Apr 2021 17:04:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:23
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 17:04:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:23
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'prevention of nausea while hospitalized'	(b) (4), (b) (6)	19 Apr 2021 17:04:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:23
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '4'	(b) (4), (b) (6)	19 Apr 2021 17:04:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:23
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Apr 2021 17:04:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:23
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:04:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:23
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'other (OTHER)'	(b) (4), (b) (6)	19 Apr 2021 17:04:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:23
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'every 6 hours as needed'	(b) (4), (b) (6)	19 Apr 2021 17:04:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:23
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	19 Apr 2021 17:04:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:24:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:23
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:04:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:23
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 17:04:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:23
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 17:04:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:23
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:04:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:23
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '05 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 17:04:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:23
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:04:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:23
User entered empty.	System	19 Apr 2021 17:04:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:23
User entered empty.	System	19 Apr 2021 17:04:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:23
User entered empty.	System	19 Apr 2021 17:04:26

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:29
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PHENOTHIAZINE DERIVATIVES, PRODUCT: PROMETHAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:06:13
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 10:06:13
Data point term sent to Coder	System	19 Apr 2021 17:05:55
User entered 'promethazine'	(b) (4), (b) (6)	19 Apr 2021 17:05:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:29
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 17:05:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:29
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'prevention of nausea during hospitalization '	(b) (4), (b) (6)	19 Apr 2021 17:05:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:29
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '12.5'	(b) (4), (b) (6)	19 Apr 2021 17:05:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:29
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Apr 2021 17:05:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:29
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:05:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:29
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'other (OTHER)'	(b) (4), (b) (6)	19 Apr 2021 17:05:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:29
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'every 6 hours as needed'	(b) (4), (b) (6)	19 Apr 2021 17:05:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:29
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Apr 2021 17:05:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:29
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:05:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:29
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 17:05:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:29
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 17:05:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:29
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:05:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:29
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '05 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 17:05:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:29
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:05:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:29
User entered empty.	System	19 Apr 2021 17:05:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:29
User entered empty.	System	19 Apr 2021 17:05:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:29
User entered empty.	System	19 Apr 2021 17:05:31

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:33
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PHENOTHIAZINE DERIVATIVES, PRODUCT: PROMETHAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 10:06:12
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 Apr 2021 10:06:12
Data point term sent to Coder	System	19 Apr 2021 17:06:56
User entered 'promethazine'	(b) (4), (b) (6)	19 Apr 2021 17:06:21

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:33
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 17:06:21

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:33
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'prevention of nausea during hospitalization'	(b) (4), (b) (6)	19 Apr 2021 17:06:21

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:33
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '12.5'	(b) (4), (b) (6)	19 Apr 2021 17:06:21

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:33
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Apr 2021 17:06:21

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:33
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:06:21

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:33
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'other (OTHER)'	(b) (4), (b) (6)	19 Apr 2021 17:06:21

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:33
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'every 6 hours as needed'	(b) (4), (b) (6)	19 Apr 2021 17:06:21

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:33
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	19 Apr 2021 17:06:21

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:33
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:06:21

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:33
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 17:06:21

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:33
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 17:06:21

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:33
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:06:21

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:33
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '05 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 17:06:21

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:33
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:06:21

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:33
User entered empty.	System	19 Apr 2021 17:06:21

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:33
User entered empty.	System	19 Apr 2021 17:06:21

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:33
User entered empty.	System	19 Apr 2021 17:06:21

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:39
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, PRODUCT: SIMETICONE, PRODUCTSYNONYM: SIMETHICONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 17:08:38
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 Apr 2021 17:08:38
Data point term sent to Coder	System	19 Apr 2021 17:07:57
User entered 'simethicone'	(b) (4), (b) (6)	19 Apr 2021 17:07:16

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:39
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 17:07:16

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:39
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'prevention of pain while hospitalized'	(b) (4), (b) (6)	19 Apr 2021 17:07:16

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:39
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '80'	(b) (4), (b) (6)	19 Apr 2021 17:07:16

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:39
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Apr 2021 17:07:16

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:39
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:07:16

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:39
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'other (OTHER)'	(b) (4), (b) (6)	19 Apr 2021 17:07:16

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:39
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'every 4 hours as needed'	(b) (4), (b) (6)	19 Apr 2021 17:07:16

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:39
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Apr 2021 17:07:16

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:24:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:39
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:07:16

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:39
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 17:07:16

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:39
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 17:07:16

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:39
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:07:16

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:39
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '05 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 17:07:16

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:39
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:07:16

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:39
User entered empty.	System	19 Apr 2021 17:07:16

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:39
User entered empty.	System	19 Apr 2021 17:07:16

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:39
User entered empty.	System	19 Apr 2021 17:07:16

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:24:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 17:08:38
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 Apr 2021 17:08:38
Data point term sent to Coder	System	19 Apr 2021 17:07:57
User entered 'vitamin D'	(b) (4), (b) (6)	19 Apr 2021 17:07:46

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 17:07:46

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'supplement'	(b) (4), (b) (6)	19 Apr 2021 17:07:46

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '2000'	(b) (4), (b) (6)	19 Apr 2021 17:07:46

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:24:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Other (OTHER)'	(b) (4), (b) (6)	19 Apr 2021 17:07:46

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:24:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'units'	(b) (4), (b) (6)	19 Apr 2021 17:07:46

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:24:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Apr 2021 17:07:46

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:24:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:07:46

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:24:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Apr 2021 17:07:46

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:24:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 17:07:46

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '04 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 17:07:46

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 17:07:46

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:07:46

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:24:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered '05 Feb 2021'	(b) (4), (b) (6)	19 Apr 2021 17:07:46

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:44
User signature succeeded.	William Smith (b) (4)	23 Apr 2021 21:39:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:45:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 17:07:46

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:24:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:44
User entered '1'	System	19 Apr 2021 17:07:46

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:44
User entered '1'	System	19 Apr 2021 17:07:46

US3712064

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:24:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:26:44
User entered '804 (804)'	System	19 Apr 2021 17:07:46

US3712064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:24:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:21:12
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:28:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 21:41:53
User closed query 'Subject had a left hip replacement. please ensure to update procedure page.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 21:41:52
Query 'Subject had a left hip replacement. please ensure to update procedure page.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 17:45:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 17:45:34
User opened query 'Subject had a left hip replacement. please ensure to update procedure page.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 16:57:47
User entered 'No (N)'	(b) (4), (b) (6)	04 Feb 2021 14:53:50

US3712064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:24:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:41:47
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:45:49

US3712064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:24:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:41:47
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'left hip replacement'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:45:49

US3712064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:41:47
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:45:49

US3712064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:24:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:41:47
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:45:49

US3712064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:24:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:27:39
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:03:14
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:28:28
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 11:59:19

US3712064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:24:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:27:39
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:03:14
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:28:28
User entered 'Left hip x-ray'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 11:59:19

US3712064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:24:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:27:39
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:03:14
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:28:28
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 11:59:19

US3712064

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:24:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:27:39
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:03:14
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:28:28
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 11:59:19

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'USA-US068-2021-MRNA-1273-P301000013'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Yes (Y)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Yes (Y)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Yes (Y)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'William'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Smith'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 19:32:34
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered empty.	System	02 Mar 2021 14:53:26
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:50:40

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:32:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered empty.	System	02 Mar 2021 14:53:26
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:50:40

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:32:39
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered empty.	System	02 Mar 2021 14:53:26
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:50:40

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:07:04
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered (b) (4) '	System	02 Mar 2021 14:53:26
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:50:46
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 22:50:46
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:50:46
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered (b) (4) '	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 16:17:02
User entered 'US'	System	18 Feb 2021 19:47:11

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	15 Apr 2021 19:20:27
User entered '4'	System	31 Mar 2021 17:54:42
User entered '3'	System	02 Mar 2021 14:53:26
User entered '2'	System	24 Feb 2021 16:17:19
User entered '1'	System	18 Feb 2021 19:47:11

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered		
'USA-US068-2021-MRNA-1273-P301000013'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Yes (Y)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Yes (Y)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Yes (Y)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'William'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Smith'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 19:32:34
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered empty.	System	02 Mar 2021 14:53:26
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:50:40

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:32:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered empty.	System	02 Mar 2021 14:53:26
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:50:40

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:32:39
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered empty.	System	02 Mar 2021 14:53:26
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:50:40

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:07:04
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered (b) (4)	System	02 Mar 2021 14:53:26
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:50:46
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 22:50:46
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:50:46
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered (b) (4) '	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 16:17:02
User entered 'US'	System	18 Feb 2021 19:47:11

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	15 Apr 2021 19:20:27
User entered '4'	System	31 Mar 2021 17:54:42
User entered '3'	System	02 Mar 2021 14:53:26
User entered '2'	System	24 Feb 2021 16:17:19
User entered '1'	System	18 Feb 2021 19:47:11

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:24:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:41
User entered '18/Feb/2021 14:47'	System	18 Feb 2021 19:47:11

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:24:11

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)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 16:17:02
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 19:47:11

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered		
'USA-US068-2021-MRNA-1273-P301000013'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Yes (Y)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Yes (Y)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Yes (Y)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'William'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Smith'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 19:32:34
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered empty.	System	02 Mar 2021 14:53:26
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:50:40

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:32:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered empty.	System	02 Mar 2021 14:53:26
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:50:40

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:32:39
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered empty.	System	02 Mar 2021 14:53:26
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:50:40

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:07:04
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered (b) (4)	System	02 Mar 2021 14:53:26
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:50:46
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 22:50:46
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:50:46
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered (b) (4)	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 16:17:02
User entered 'US'	System	18 Feb 2021 19:47:11

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	15 Apr 2021 19:20:27
User entered '4'	System	31 Mar 2021 17:54:42
User entered '3'	System	02 Mar 2021 14:53:26
User entered '2'	System	24 Feb 2021 16:17:19
User entered '1'	System	18 Feb 2021 19:47:11

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:24:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:41
User entered '24/Feb/2021 11:17'	System	24 Feb 2021 16:17:19

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:24:11

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)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:53:30
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:47:41
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 16:17:19

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered		
'USA-US068-2021-MRNA-1273-P301000013'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Yes (Y)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Yes (Y)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Yes (Y)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'William'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Smith'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 19:32:34
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered empty.	System	02 Mar 2021 14:53:26
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:50:40

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:32:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered empty.	System	02 Mar 2021 14:53:26
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:50:40

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:32:39
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered empty.	System	02 Mar 2021 14:53:26
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:50:40

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:07:04
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered (b) (4)	System	02 Mar 2021 14:53:26
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:50:46
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 22:50:46
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:50:46
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered (b) (4) '	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 16:17:02
User entered 'US'	System	18 Feb 2021 19:47:11

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	15 Apr 2021 19:20:27
User entered '4'	System	31 Mar 2021 17:54:42
User entered '3'	System	02 Mar 2021 14:53:26
User entered '2'	System	24 Feb 2021 16:17:19
User entered '1'	System	18 Feb 2021 19:47:11

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:24:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:07:04
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '02/Mar/2021 09:53'	(b) (4) System	02 Mar 2021 14:53:26

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:24:11

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 22:07:04
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 14:53:26

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered		
'USA-US068-2021-MRNA-1273-P301000013'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Yes (Y)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Yes (Y)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Yes (Y)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'William'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Smith'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 19:32:34
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered empty.	System	02 Mar 2021 14:53:26
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:50:40

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:32:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered empty.	System	02 Mar 2021 14:53:26
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:50:40

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:32:39
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered empty.	System	02 Mar 2021 14:53:26
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:50:40

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:07:04
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered (b) (4) '	System	02 Mar 2021 14:53:26
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:50:46
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 22:50:46
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:50:46
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered (b) (4) '	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 16:17:02
User entered 'US'	System	18 Feb 2021 19:47:11

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	15 Apr 2021 19:20:27
User entered '4'	System	31 Mar 2021 17:54:42
User entered '3'	System	02 Mar 2021 14:53:26
User entered '2'	System	24 Feb 2021 16:17:19
User entered '1'	System	18 Feb 2021 19:47:11

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:24:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:07:04
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
User entered '31/Mar/2021 13:54'	(b) (4) System	31 Mar 2021 17:54:42

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:24:11

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 22:07:04
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 12:52:03
User entered 'I'	(b) (4), (b) (6)	31 Mar 2021 17:54:42

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered		
'USA-US068-2021-MRNA-1273-P301000013'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Yes (Y)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Yes (Y)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'No (N)'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Yes (Y)'	System	18 Feb 2021 19:46:46

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'William'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered 'Smith'	System	18 Feb 2021 19:46:46

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

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[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 19:32:34
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered empty.	System	02 Mar 2021 14:53:26
User entered '801 NORTH WEISGARBER'	(b) (4), (b) (6)	25 Feb 2021 22:50:40

US3712064

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Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:32:37
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered empty.	System	02 Mar 2021 14:53:26
User entered 'Knoxville'	(b) (4), (b) (6)	25 Feb 2021 22:50:40

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 19:32:39
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered empty.	System	02 Mar 2021 14:53:26
User entered 'TN'	(b) (4), (b) (6)	25 Feb 2021 22:50:40

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 10 Jun 2021 09:24:11

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:07:04
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:53:30
User entered (b) (4)	System	02 Mar 2021 14:53:26
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 22:50:46
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 22:50:46
User entered '37909' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 22:50:46
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:47:04
User entered (b) (4)	System	18 Feb 2021 19:46:46

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	05 Apr 2021 00:15:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 18:47:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 16:17:02
User entered 'US'	System	18 Feb 2021 19:47:11

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	15 Apr 2021 19:20:27
User entered '4'	System	31 Mar 2021 17:54:42
User entered '3'	System	02 Mar 2021 14:53:26
User entered '2'	System	24 Feb 2021 16:17:19
User entered '1'	System	18 Feb 2021 19:47:11

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:24:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:28:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:29:13
User entered '15/Apr/2021 15:20'	System	15 Apr 2021 19:20:27

US3712064

Folder: SAE USA-US068-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

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Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	William Smith (b) (4)	18 Apr 2021 23:28:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:29:13
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:20:32
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 19:20:27